# MISSOURI'S PLANNING GUIDE FOR LOCAL MASS PROPHYLAXIS: DISTRIBUTING AND DISPENSING THE STRATEGIC NATIONAL STOCKPILE

## A Guide for Local Planning

*Version 2 – DRAFT*

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**MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES**

***Supercedes previous draft***

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## INTRODUCTION

If a terrorist attacks or a major natural disaster or a technological accident occurs, state and local jurisdictions probably will deplete the supplies of pharmaceuticals and other medical items rapidly. Anticipating this situation, congress established a massive stockpile of pharmaceuticals, vaccines, medical supplies, equipment, and other items to augment local supplies of critical medical items. That stockpile, managed by the U.S. Department of Homeland Security, in coordination with the Centers for Disease Control Prevention (CDC), is known as the Strategic National Stockpile (SNS).

The Missouri Department of Health and Senior Services (DHSS) has a plan to request, receive, and distribute the SNS to local public health agencies (LPHAs), hospitals, and EMS providers. The State will distribute the contents of the stockpile at six state distribution sites (number of distribution sites open will depend on the location and size of the event, see Attachment 2 for a map of the sites). Due to security reasons, the location of these sites will not be made known to the LPHAs, hospitals, and EMS providers until the time of the event. Additional state distribution sites will be added in the future.

While the receipt and distribution of the stockpile is a monumental task, this is a small part of what needs to be done in order to get necessary medicines and medical supplies to the residents and guests of Missouri. The dispensing process is the most challenging and labor intensive function of the SNS management. LPHAs must be prepared to receive their portion of the stockpile should a biological emergency arise. The LPHAs must plan for mass pharmaceutical dispensing, as well as mass vaccination. Hospitals must plan for the treatment of staff, their families, as well as patients. Hospitals must also address how their facility will handle a surge capacity of large numbers of individuals presenting for treatment as a result of a terrorist event.

This guidance is intended to assist local planning committees develop a plan and procedures needed to respond to a major public health emergency requiring prophylactic and medical treatment. Much of the guidance is adapted from the CDC's Guide for Receiving, Distributing, and Dispensing the Strategic National Stockpile (formally the SNS) Version 9 – Draft, April 2002. The logistics and planning that is involved for pharmaceutical dispensing also applies to running a large vaccination clinic. This guidance is also intended to assist LPHAs and hospitals in determining how to efficiently treat large numbers of individuals while maintaining current requirements under MO state statutes.

All LHPAs are required to use this guide in the development of their local emergency response plan for dispensing life saving drugs as a result of a natural or terrorist event. The plan for the management and dispensing of the Strategic National Stockpile is to be sent to the Department of Health and Senior Services (DHSS), Center for Emergency Response and Terrorism (CERT) via E-mail or on a CD disk. For assistance in any part of the planning or questions related to this guidance, please call the CERT at 573-526-4768.

## CHAPTER 1: PLANNING

This chapter discusses the planning process that needs to be included in the local plan. In many Missouri counties local planning committees have already formed to address issues related to bioterrorism (BT). These groups have also been used to develop and refine plans for dispensing pharmaceuticals or vaccinating the citizens in their respective counties. In many areas counties have come together to plan a multi-county approach for mass prophylaxis planning. Since the need for mass prophylaxis would be the result of a public health emergency, the LPHA should take the lead in the planning for a mass prophylaxis process.

Consistent terminology is extremely important in any planning process at the state and local level. For this reason local plans should:

1. Define specialized terms and abbreviations to assure all participants use the same definition

**Missouri will use the following terms and definitions in both state and local plans:**
Table 1-1. Definition of Terms

| |
|---|
| 1. CDC: The Centers for Disease Control and Prevention |
| 2. RSS: Receiving, Staging, and Storage Site for SNS (state responsibility). |
| 3. ADS: Area Distribution Site for the SNS (state responsibility). |
| 4. Distribution: The process of providing the SNS from a RSS or ADS to local public health agencies, treatment centers, community health centers, emergency medical system providers, or private physicians. (state responsibility) |
| 5. Dispensing Sites: The community locations where the public receives prophylactic medicines (local responsibility). |
| 6. SNS Program: The Strategic National Stockpile Program. |
| 7. SNS: The Strategic National Stockpile of drugs and other medical materiel that CDC will deliver to a state. |
| 8. Prophylactic Drugs: The drugs that protect against biological threats, such as anthrax. |
| 9. TARU: The SHS Program's Technical Advisory Response Unit of skilled individuals who arrive with the first shipment of the SNS to assist state and local officials. |
| 10. Treatment Centers: The locations in a community where the sick receive treatment. These include hospitals, clinics, and other sites that treat the sick. and injured. |
| 11. Materiel: Contents of the 12-hour Push Package or the Vendor Managed Inventory |

2. Clearly define essential community participants and delineate responsibilities, including:
   - Local Public Health Agency
   - Local Emergency Planning Committee
   - Local law enforcement
   - Local fire protection
   - Physicians
   - Pharmacies
   - Hospitals and treatment centers (including Ambulatory Surgery Centers)
   - Community Health Centers
   - Retired licensed professionals (such as nurses, physicians, pharmacist, social workers, and psychologists)
   - Churches
   - School systems
   - EMS providers
   - Funeral Homes
   - Long Term Care Facilities
   - Private business (such as large community employers)
   - Government leaders (county and city)

3. Designate the LPHA as the lead agency of the planning committee. The LPHA should:
   - Ensure that all members of the planning committee are familiar with this guidance.
   - Provide information on the contents of the Strategic National Stockpile (SNS).
   - Provide information on the Federal and State role in SNS management.

*The DHSS Center for Emergency Response and Terrorism (CERT), SNS Program Manager and the state planners can assist by providing information and training for committee members. For assistance contact Angela Ford, (573) 526-4768, E-mail, forda@dhss.mo.gov*

4. Define local antibiotic inventories required to protect the essential first responders. The LPHA needs to determine:
   - the quantity of the antibiotics that you need in your local resources; and
   - the location of the local resources so they are convenient to essential personnel when they need it.

5. Determine credentialing process of local SNS team, this includes:
   - authorization of select members to attend local intelligence briefings;
   - proper identification;
   - training;
   - job activity sheets for SNS team;
   - role definition prior to the event; and
   - exercise and evaluate SNS team response.

## Chapter One Summary: At a minimum, the plan should include:

- **terminology that is consistent with the state terminology;**
- **contacts with support organizations/agencies, partnerships, and facilities that support your local SNS plan to make sure all required resources are available to respond;**
- **determine local medical resources (includes antibiotics and medical supplies);**
- **a process to conduct SNS orientation and individual/functional group training; and**
- **procedures for credentialing your local SNS team to ensure their access to relevant information about an emergency and to the areas they must serve and work in.**

## CHAPTER 2: COMMAND AND CONTROL

This chapter discusses the way the community manages its response to a public health emergency that requires mass prophylaxis. The structure and operation of the command and control (C&C) function typically will be a part of a broader local all hazards or bioterrorism response plan, and thus, not part of the local SNS plan for receiving and dispensing the SNS. However, communities must identify how the local SNS team leaders will interact with the local C&C function to report operational status and problems. The Department of Health and Senior Services (DHSS) SNS program manager and the State Emergency Management Agency (SEMA) area coordinator will provide technical assistance to the local C&C authority upon request.

### 2.1 SNS Team interactions with local emergency operations center (LEOC)

Local event command and control actions typically occur in an LEOC where political leaders, emergency managers, public health and law enforcement officials, and others work side by side to evaluate information about an emergency and to manage their response to it. It is recommended that a liaison from the LPHA be available to the LEOC who can:

- Answer leadership's questions about the SNS.
- Clarify leadership information and guidance to the local SNS team.
- Explain the local SNS team's operational status reports if necessary.

The SNS team liaison should be able to report the following to the LEOC:

- Status of SNS inventory levels, including replenishment actions when existing supplies run low and apportionment when demand exceeds existing supplies.
- Status of deliveries (timeliness and frequency) to dispensing sites, treatment centers, and other locations.
- Operational problems that delay the delivery of materiel.

### 2.2 SNS Team interactions with the DHSS Department Situation Room (DSR)

During an event the DHSS DSR will be activated. A liaison from the local level should be available who can communicate via telephone, e-mail, or fax to the DSR to:

- Answer leadership's questions about the SNS materiel designated for the community.
- Clarify information related to the plan.
- Report on the status of the SNS inventory sent to the community.
- Request materiel for local dispensing from the SNS.

### 2.3 Critical C&C Issues

Regardless of the structure of the local all hazards or bioterrorism response plan, the following information should be included in the plan;

- Chain of Command—How will your local SNS team leadership communicate with the LEOC(s)? *This is especially important in multi-state or multi-jurisdictional areas*.
- Decision Making—Who has the authority and what is the process for making decisions about the organization and management of the SNS?
- Information Monitors—Who will manage and monitor the flow of real-time information from and between different SNS functions for supporting the overall SNS operations?

2.4 Multi-County and Regional C&C Issues

When a threat affects multiple jurisdictions, the structure and operation of the C&C function becomes considerably more complex but also more important for effectively receiving, distributing, and dispensing SNS materiel. If a county or community is collaborating with other LPHAs, the plan should state which agency would assume the lead role for receiving the SNS from the state. Thus, it is strongly suggested that multi-county and regional plans establish methods for:

- coordinating their request for the SNS;
- identifying specific individuals authorized to accept the SNS;
- deciding on a local warehouse (centrally located) to serve as the local distribution site (this facility must meet the security and storage requirements that are stated in the state SNS plan);
- identifying how to staff and secure receipt, storage, and dispensing functions;
- determining how much to distribute initially to each dispensing site and treatment center on the basis of data about health (case count), epidemiological, intelligence, or inventory availability and sending that information to the SNS program manager in the Department Situation Room, DHSS; and
- coordinating the release of information to the public, private health providers, and treatment facilities.

## Chapter 2 summary: At a minimum, the plan should include:

- **how the local SNS team will interact with the LEOC;**
- **how the local SNS team will interact with the DHSS DSR;**
- **identification of the local SNS team person assigned to communicate with the LEOC;**
- **chain of command, including who manages the SNS; and**
- **multi-county and/or regional management of the SNS.**

## CHAPTER 3: JUSTIFICATION FOR REQUESTING THE SNS

This chapter discusses the justification process that LPHAs will follow to request the SNS. The decision to request assistance from the SNS must be determined by evidence-based epidemiological data that demonstrates local resources are not sufficient to treat the numbers of individuals who are ill or exposed.

The decision to request the SNS from the SNS Program through the Centers of Disease Control and Prevention (CDC) will be a collaborative effort between local, state, and federal officials. It will start at a local level when officials identify a potential or actual problem that they believe will threaten the health of their community. Local officials, in collaboration with the LPHA, will contact the DHSS and request assistance from the SNS Program. The Director of the DHSS, in collaboration with the CDC, Homeland Security, and SEMA, will notify the governor's office if the problem appears to be serious enough to require resources that local authorities may not have. If the Governor supports that conclusion, he or she formally will request the SNS directly from CDC, or include the request as part of a formal request for federal assistance through the national emergency response system.

The Director of the CDC, in coordination with the Directors of the Departments of Homeland Security (DHS) and Health & Human Services (HHS) will quickly evaluate the governor's request with local, state, and federal officials by evaluating the actual or potential threat, the status of local resources, and plans for dealing with the threat. If these officials concur that the vent has a potential to consume local resources, the Director of DHS has the authority to order the deployment of the SNS. See Table 3-1 below for a listing that CDC will use to determine if a request from Missouri is justified.

Table 3-1. Requesting the Strategic National Stockpile

| Request Justification |
|---|
| Overt release of a chemical or biological agent |
| Claim of release by intelligence or law enforcement |
| Indication from intelligence or law enforcement of a likely attack |
| Clinical or epidemiological indications |
| Large number of ill persons with similar disease or syndrome |
| Large number of unexplained disease, syndrome, or deaths |
| Unusual illness in a population |
| Higher than normal morbidity and mortality from a common disease or syndrome |
| Failure of a common disease to respond to usual therapy |
| Single case of disease from an uncommon agent |
| Multiple unusual or unexplained disease entities in the same patient |
| Disease with unusual geographic or seasonal distribution |
| Multiple atypical presentations of disease agents |
| Similar genetic type in agents isolated from temporally or spatially distinct sources |
| Unusual, genetically engineered, or antiquated strain of the agent |
| Endemic disease or unexplained increase in incidence |

Table 3-1. Requesting the Strategic National Stockpile

| Request Justification |
|---|
| Simultaneous clusters of similar illness in non-contiguous areas |
| Atypical aerosol, food, water transmission |
| 3 people presenting the same symptoms near the same time |
| Deaths or illness among animals that precedes or accompanies human death |
| Illnesses in people not exposed to common vent systems |
| Laboratory results |
| Unexplainable increase in emergency medical service requests |
| Unexplained increase in antibiotic prescriptions or over-the-counter medication use |

Note that CDC does not have to wait for the president to activate the Federal Response Plan (FRP) to deploy the SNS. During terrorist attacks in the fall of 2001, for instance, SNS shipped materiel to New York City before the president activated the FRP. Also note that the Missouri Governor does not have to declare a state of emergency to request assistance from the SNS.

3.1 Surveillance:

Missouri's decision to request the SNS will be based on sentinel and active surveillance accomplished through a collaborative effort between the state health department, local public health departments, and local treatment facilities. Together, sentinel and active surveillance are an epidemiological evidenced-based system for the detection of possible biological, chemical and radiological events, and the consistent reporting of all incidents. The DHSS will maintain sentinel surveillance throughout Missouri through one hundred sites; the 115 LPHAs will maintain active surveillance at the community level.

- Sentinel Surveillance:
  - The 100 sentinel surveillance sites are strategically located throughout the state consisting of, but are not limited to, hospitals, Federally Qualified Health Centers, Rural Health Clinics, physician practices, schools, large employers, and animal confinement operations.
  - The sites were selected based on population and catchment areas of the facility, as well as key places individuals would go to get medical attention.
  - The sites were also chosen based on state assets that may attract a terrorist attack.
  - The 100 sentinel sites will report directly to the DHSS, Division of Environmental Health and Communicable Disease Prevention (DEHCDP), Office of Surveillance (OoS) on a daily basis, data will be evaluated and entered into a surveillance database.
  - The LPHAs will be notified immediately regarding areas of concern.
  - Based on the surveillance reporting, GIS mapping will be done within the DHSS.

- Active Surveillance:

- Through the Core Public Health Contract (CPHC), the LPHAs will perform active surveillance in their respective geographic area of responsibility.
- The CPHC requires the LPHAs have enough surveillance sites to access the disease patterns and status within the communities in their geographic area of responsibility.
- The LPHAs will contact their designated sites and report the data to the DHSS.
- The LPHA bioterrorism epidemiological specialist will immediately report concerns of the hospitals, pharmacies, and health care providers to the DHSS.

- Health Care Provider Participation:
  - Identified sites will actively participate in sentinel and/or active surveillance.
  - Community health care providers will engage in planning with the LPHAs for active surveillance.
  - Community pharmacies will participate by reporting excessive sales of over-the-counter (OTC) medications that treat symptoms of a biological agent to the LPHA.
  - Local health care providers and treatment facilities will immediately report concerns to the LPHA.

The DHSS impetus for surveillance efforts is the belief that early identification of health threats maximizes the results of prevention efforts. This will be accomplished by promoting collaboration among partners in their efforts at collecting data using existing methods and by helping to implement a unified statewide surveillance system that will ultimately replace multiple systems of data collection.

3.2 Investigation

- Investigation of cases with suspected illness will begin at the LPHA. Situations or conditions that can prompt case investigations include but are not limited to:
  - Large numbers of ill persons with similar disease of syndrome
  - Large number of unexplained disease, syndrome or deaths
  - Unusual illness in a selected population (e.g., outbreak of severe rash illness affecting adults)
  - Endemic disease with unexplained increased incidence
  - Report by the LPHA, physician, hospital or media

- If the LPHA requests assistance from the DHSS with investigation they should:
  - follow the process of investigation and/or reported incident or threat; and
  - request assistance with investigation and report an incident or threat, to the DSR 24/7 at 1-800-392-0272 (upon notification the DSR will implement the DHSS call down procedures).

## Chapter 3 summary: At a minimum, the plan should include:

- **the process your LPHA utilizes to maintain active surveillance in the community;**

- **the name of the person responsible for monitoring the surveillance related to a biological event;**
- **the process your LPHA utilizes to conduct a case investigation based on evidence-based data:**
- **the number of individuals local providers (pharmacies, physicians, treatment facilities etc) can treat before local resources of antibiotics and medical supplies is exhausted; and**
- **the name of local official, or designee, authorized to request the SNS.**

## CHAPTER 4: REQUESTING THE SNS

In order for Missouri to request the SNS (both the 12-hour Push Package and Vendor Managed Inventory (VMI)), local resources must have been identified and exhausted. Based on this, each LPHA and hospital must state in their plan how many individuals can be treated before outside resources are needed. For this reason, the local plan must state the number of individuals to be treated, and the amount of medication available from the local level. (Since there is not a minimum number who must be treated with local resources, communities and hospitals are not encouraged to stockpile medications. It is suggested that hospitals be self-sufficient for a three-day period.)

### 4.1 Local Resources

Special populations should be considered when determining the limit of the local resources. For instance, high tourist areas, lake areas, and amusement parks will have seasonal populations of individuals from other states and countries. Local plans must take this into account and have adequate plans for treatment of these individuals.

Special health care needs populations must also be considered. This includes children and adults with illnesses who are cared for in their homes. The DHSS Bureau of Special Health Care Needs and Section of Senior Services have collaborated in the development of a checklist for contract providers to utilize when developing client care plans to assure that the needs of their homebound clients are addressed. Many of these individuals will not be able to sustain life without assistance from an in-home provider. LPHAs and local hospitals should collaborate with the contract providers to assure that this population will be adequately cared for during an event.

Although the federal government will supply the medications needed for military personnel and their families; local communities are encouraged to include any military personnel in the population mix for prophylaxis. Including this population will give the community a more accurate estimate of the numbers of individuals who have the potential to become ill. Communities with colleges should include the student population in the population mix.

In order to accurately determine the limit of local resources, the local SNS plan must include the following:

- Identification of community-based pharmacies that can provide antibiotics for initial treatment of local first responders, this includes
  - Personnel of the LPHA
  - Fire department
  - Law enforcement
  - Emergency medical services providers
  - Key government leaders
  - Volunteers who will support the local dispensing function
  - Family members of the above

- Identification of community-based pharmacies that can provide antibiotics for the treatment of individuals ill or exposed to the event.
- Estimation of number of individuals who can be treated with local resources.
- Identification of special population groups, including but not limited to:
    - Seasonal tourists (such as summer population vs. winter population of Branson)
    - Tourists from other states and countries
    - Individuals attending concerts, ballgames, shopping (short-term event)
    - Individuals attending amusement parks, camping (longer-term event)
    - Seasonal workers (such as summer resort and lake employees)
    - Students on school trips
    - College students (summer vs. other seasons)
    - Senior citizen tours
    - Influx of non-Missouri resident workers (such as Illinois residents working in St. Louis)
    - Influx of state employees Monday – Friday (such as in Jefferson City)
- Identification of special needs populations, including but not limited to:
    - Home bound individuals (such as elderly and/or disabled)
    - Homeless individuals
    - Individuals residing illegally
    - Migrant workers
    - Hospital patients
    - Long term care facility patients

*NOTE: The DHSS will provide antibiotics for initial treatment of state employees (and their families) who are listed as first responders, this includes staff within the DHSS, Highway Patrol, Department of Natural Resources, SEMA, the Governor's office, and other state personnel who have been identified as first responders. The DHSS will not supply treatment for all DHSS employees, or their families, or other state employees (other than those mentioned above).*

*State employees who are not first responders will be treated with the general population at local dispensing sites. LPHAs located in areas with a high number of state employees should take this into consideration when they plan for the population needing prophylaxis. Many state employees will want to pick up medications in the area where they work, not necessarily where they live.*

4.2 Contacting the DHSS

The initial request for assistance should be made by telephone call to the DSR (1-800-392-0272) by the local authority in collaboration with the LPHA. DSR staff will process the call according to the DHSS SNS request protocol. During the course of the event all requests for the SNS must be made through the DSR.

- The following information must be included in the local plan:
    - title of the individual(s) within local jurisdiction authorized to request the SNS;

- name of the individual within the LPHA authorized to submit documentation to the DHSS requesting SNS materiel, and 24/7 contact information;
- 24/7 contact number of the LPHA if different from the above number; and
- a redundant plan for contacting the DHSS if phone lines are down (the DHSS suggest you discuss this issue with your local law enforcement, regional state highway patrol, and SEMA area coordinator).

- The following information must be submitted to the DSR at the time of the request:
  - number of individuals treated before local resources were exhausted;
  - number of local first responders (and their families) treated;
  - number of individuals currently showing symptoms or ill;
  - projected needs considering the population, including transients, and possible number infected versus non-infected individuals;
  - number of current casualties;
  - location of dispensing site(s) that will be opened;
  - name and location of the hospital(s) involved in the event;
  - hospital capacity at the time of the event, including ICU beds and ventilator needs;
  - local resources identified, including pharmacy distributors, oxygen availability, other nearby hospitals, transport capacity, and local alternative care centers;
  - security measures at the dispensing site(s); and
  - copy of signed physician orders (if plan does not contain signed document).

*(A template including the above information will be made available to the LPHAs by December 2003.)*

## Chapter 4 summary: At a minimum, the plan should include:

- **identification of community-based pharmacies that will provide treatment prior to SNS;**
- **identification of special population groups;**
- **identification of special health care needs population;**
- **the title of the local authority who will contact DHSS requesting the SNS;**
- **method of communication with the DHSS requesting the SNS, including redundant plan;**
- **location of dispensing sites;**
- **number of individuals that can be treated with local resources; and**
- **the name of LPHA staff that will collaborate with the DHSS when the SNS is requested.**

## CHAPTER 5: MANAGEMENT OF THE SNS

This chapter discusses management of the SNS at the local level.

At the time that Missouri requests the SNS, the local plan(s) of the area where the event is occurring will be forwarded to the CDC. The plan(s) must contain how the SNS will be managed at the local level; therefore, the local plan must contain detailed information.

5.1 Pick up from State Distribution Site(s)

It will be the responsibility of the LPHA and/or hospital to pick up the SNS medication and supplies from a state distribution site. The (local) authorized person will be required to sign for the SNS at the state distribution site(s) (attachment 1). SNS materiel will not be released without either prior authorization of named individuals to the CERT, or the individual has written authorization from the LPHA. Individuals picking up the SNS must show a photo ID. Due to security reasons, state distribution site(s) will not be made public. The LPHAs and hospitals will be given the exact location of the distribution site(s) at the time of the event. It is imperative that LPHAs and hospitals not share with the media the location of the distribution site(s).

LPHAs may want to have a collaborative plan with local hospitals to identify the most efficient method to pick up the medication and supplies from the state distribution site(s). LPHAs may also want to participate in a multi-county plan naming one county as the lead in the SNS management.

- The local plan must include the following:
  - name of the LPHA designated as the lead in a multi-county plan (if applicable);
  - name of hospitals participating in collaboration with the LPHA, (if applicable);
  - name of individual authorized to receive SNS from the state distribution site(s);
  - individual registered with DEA and MO Bureau of Narcotics and Dangerous Drugs (BNDD), if applicable;
  - method of credentialing individual authorized to receive materiel;
  - location of local distribution site if materiel is not delivered directly to hospitals or dispensing site(s);
  - name and contact number of individual responsible for SNS management;
  - method of transport of materiel from the state distribution site(s) to local site;
  - method of transport of materiel from local distribution site to dispensing site(s); and
  - method of security during transport.

Local planning committees will need to plan now for the size of vehicle needed to pick up the boxes of medications for the dispensing sites. If an LPHA agrees to pick up supplies and medication for a hospital, the plan should indicate how the medication and supplies are to be transported. If a hospital request medication that falls within the substance II criteria, and the LPHA is picking up the medication, the LPHA must have a pharmacist that is DEA registered

sign for custody. Because the materiel must be secure in transport, the plan must state the method that will provide security during transportation to the dispensing sites. The state distribution site(s) are strategically located throughout the state so that only a small area in the state is over 90 miles from any one site, that area is Atchison and upper Nodaway County (see attachment 2).
Utilize the table below to calculate the size of vehicle needed to transport boxes of medication to dispensing site(s); the dimensions are in inches. (Additional state distribution sites will be added in the future)

| Product | Pills Per Bottle | Bottles Per Case | Dimensions |
|---|---|---|---|
| **Cipro 500mg** | 20 | 100 | 12*8*8 |
| **Cipro 500mg** | 20 | 400 | 14*14*14 |
| **Cipro 500mg** | 20 | 720 | 18*18*18 |
| **Doxy 100mg** | 20 | 100 | 12*8*8 |
| **Doxy 100mg** | 20 | 400 | 14*14*14 |
| **Doxy 100mg** | 20 | 720 | 18*18*18 |
| **Doxy 100mg** | 50 | 720 | 18*18*18 |
| **Amox 200 mg** | 75 | 40 | 10*8*8 |
| **Amox 500mg** | 30 | 40 | 10*8*8 |
| **Amox 500mg** | 30 | 80 | 14*10*10 |
| **Amox 500mg** | 30 | 480 | 18*18*18 |

*Hospitals picking up medication and supplies directly from a state distribution site must provide a plan with the same information as stated above. Equipment, such as ventilators and suction machines, will be shipped directly to a hospital from the SNS.*

5.2 Dispensing Site Selection

The dispensing function provides oral drugs and vaccines to protect the public from a biological threat. It is the most complex of all SNS plan functions. It includes the following activities:

- Set up, secure and operate a highly efficient operation that serves thousands (perhaps hundreds of thousands) of people quickly before they become symptomatic.
- Locate and coordinate the use of highly skilled, but relatively scarce pharmacists, doctors, and nurses to staff and manage dispensing operations.
- Recruit, train and organize many volunteers to perform the majority of dispensing site functions.
- Isolate symptomatic individuals and transport them to treatment centers.
- Provide the public comprehensive, accurate, reassuring information about community efforts to protect them from a threat.

For dispensing to be effective, it must have enough capacity to protect potentially affected population in time to prevent the onset of symptoms. When creating the plan, assume a worst-case scenario and plan sufficient sites with sufficient capacity to provide prophylaxis to the entire community. If the plan is for a wide-scale event, it will be easy to scale down for a more limited event. It will be extraordinarily difficult, however, to scale it up if the plan is only for a limited event.

Hospitals, community health clinics, walk-in clinics, and private physician offices should not be utilized as dispensing sites for the general population. In the event that the agent is unknown, ill individuals need to be kept separate from the general population. Hospitals should be considered as a closed dispensing site, meaning that dispensing is limited to the employees, their families and the patients. Hospitals will need to determine if families of their patients will also be treated at the hospital. In the event that the facility is under quarantine or family members require isolation, the family members will need to be treated at the hospital. The LPHA will need to include the number of oral medication hospitals require when they request the SNS.

The DHSS recommends the following factors be considered when determining the number and location of dispensing sites:

- Scale, type, and location of an attack. These factors determine the number of people exposed (or worried about exposure) and thus the number and location of people who must be protected within a specific period. For instance:
  - Seasonal factors, does the local population increase during the summer months
  - Year round local attractions
  - Concerts and/or entertainment areas
  - Sporting events
  - National conferences or events held in Missouri
  - World events held in Missouri (example when the Pope visited St. Louis)
  - Influx of rural population to urban area for work, play, or health care
  - Influx of adjoining states residents for work, play, or health care
- Number of sites. more sites:
  - make it easier for the public to get to the sites (shorter driving distances, less congestion, possibility of walking to the sites);
  - reduce the length of the lines at sites;
  - reduce the time to get protective drugs; and
  - reduce the anxiety of those who must wait in line for the drugs.
- On the other hand, more sites:
  - require more security to protect sites, delivery vehicles, and drivers; and
  - require more staff members, particularly pharmacists, doctors, and nurses.
- Size of facilities, compared with having several small sites, larger but fewer sites:
  - may be able to process more people with the same number of pharmacists, nurses, and doctors; but
  - may pose a bigger crowd control problem because they concentrate more worried, frustrated people in one place.

- Operating hours:
  - Each site must be open 24 hours a day when the public must receive their first protective regimen.
  - Round-the-clock operation will require a large staff.
- Dispersed locations*:*
  - Sites should be in each community to preclude the perception of favoritism for parts of the population.
- Familiar locations*:*
  - Sites should be easy to find and familiar to all population groups (DHSS recommends public and/or private schools).
- Accessibility*:*
  - People should be able to use public transportation (if available) or private auto. (See our discussion later in the chapter on transporting the public during mass prophylaxis campaigns.)
- Physical characteristics*.* Sites must be big enough to handle large numbers of people under cover and out of the weather. Each site should have the following characteristics:
  - heat and air conditioning to maintain temperatures at controlled room temperature, which the U.S. Pharmacopoeia defines as the usual and customary working environment of 20°C to 25°C (68°–77°F) that allows for brief deviations between 15°C and 30°C (59°–86°F) that are experienced in pharmacies, hospitals, and warehouses;
  - storage of substance II medications must meet DEA and BNDD requirements (attachment 3 & 4);
  - have areas that can be secured for medication storage;
  - adequate bathrooms, water, and electricity;
  - designated separate area for individuals who are ill or symptomatic when they present to the dispensing site;
  - designated separate area for individuals who require attention to emotional needs;
  - designated separate area for individuals who become ill due to natural causes while waiting for medications;
  - areas for large numbers of people to receive pre-education via video;
  - area for counseling special needs populations, such as pregnant women, parents of infants, the elderly, etc;
  - loading area (for receipt of supplies);
  - space for parking at or near the sites;
  - space for landing a helicopter for supply deliveries if land travel is not possible;
  - facilities for food storage and preparation for staff and volunteers; and
  - area for workers to rest or sleep.

The DHSS recommends local schools be utilized for dispensing sites. Most schools meet the above criteria and community residents are familiar with the location of the school(s) in their area.

## 5.3 Efficient Dispensing-Site Design

The number of people the network of dispensing sites can protect per hour is a measure of its efficiency. In order to assure an efficient dispensing site consider the following:

- Design the dispensing site(s) to process many people quickly for a large-scale attack.
- Design the dispensing operation well in advance of an event.
- Include the dispensing design of each site in the plan.
- Utilize existing proven methods of large crowd control, such as the Disney concept of managing several small groups of people (30) in progressive rooms providing introductory information, to spill into a large area for the final presentation.
- Maximize the use of the facility. Several schools now have the capacity to show videos simultaneously in several classrooms.
- Minimize the use of any staff. Design a process that directs the movement of people with methods such as multi-language signage and portable crowd control barriers such as those used by airlines in ticket lines.
- Reduce the number of stops to get drugs. If a person diverts from the line for some reason—for example, check for symptoms, weigh children, or process regimen requests for family members who are not present—make sure they rejoin it at an appropriate point and do not have to start at the beginning.
- Ensure adequate support. Make sure the site has the following items:
  - equipment—label printing equipment (computers, printers, and label stock);
  - facilities—tables, chairs, lane roping, toilets, drinking water (important particularly during hot months), chairs for the young and elderly, and wheel chairs;
  - supplies—pens, pencils, paper, forms, and bottled water; and
  - specialized items—scales for weighing children, mixing equipment for pediatric portions, etc.

## Chapter 5 summary: At a minimum, the plan should include:

- **a detailed description of how the SNS materiel will be picked up from the state distribution site(s);**
- **a detailed description of dispensing site(s) selected, including location with address and a contact person for each site;**
- **a description of how the site(s) will be utilized to maximize efficiency;**
- **a description of how medication will be transferred to the dispensing site(s);**
- **a description of the method of security for each site; and**
- **a description of collaboration with the area hospital(s) if the LPHA plans to pick up hospital supplies and drugs.**

## CHAPTER 6: OPERATIONAL ISSUES

This chapter discusses operational issues of dispensing and administrating medication that the plan needs to address. In order to provide medication to large numbers of population efficiently and quickly, the plan must have standard operating procedures (SOP) that are uniform for each dispensing site. When developing the SOP consider the following:

### 6.1 Definition of Roles and Responsibilities for Staff and Volunteers

Staff members or volunteers will be needed to do the following:

- Orient the public (video or volunteer with a script)
- "Greiage" greet and triage - examine and redirect symptomatic people to treatment (healthcare professional)
- Weigh children under age 5 (volunteer)
- Replenish and reorder supplies such as labels, unit-of-use drugs, and consumable items such as pens, paper, and toilet paper (volunteer with minimal training)
- Explain dispensing-site procedures and policies, for example, whether you allow one adult to pick up drugs for an entire family and the maximum number of regimens you will provide (volunteer with training and a script)
- Hand out health assessment forms and instruct people on how to complete them (volunteer with training)
- Educate and orient people standing in line (volunteer with a script, or video)
- Explain various information, including:
    - Drugs people will receive including any pediatric medicines for children (health professional or video)
    - Importance of adhering to regimen instructions (volunteer with a script)
    - Danger of overmedicating (volunteer with script)
    - Date to return for additional regimens (volunteer)
- Check completion of health assessment forms for all people in line and those who are not present (volunteer)
- Interpret directions for people who do not speak English or are hearing impaired, deaf, or illiterate (interpreter, volunteer, and/or multi-language videos)
- Dispense oral medication (RN, physician, or pharmacist, a pharmacy technician and/or pharmacy student can only be used if a pharmacist is on-site)
- Provide technical expertise such as answering questions or prescribing an alternate drug regimen based on the patient's medical history form for conditions such as allergies, pregnancy, breast-feeding, and adverse reactions to existing medications (medical and/or pharmacy professional)
- Administer vaccinations (RN, LPN, pharmacist, or physician)
- Distribute regimens, which includes:
    - annotating required additional information on the drug label (prescription number, drug, lot, etc.) and recording the drug regimen on the person's NA form (see

section below on labeling under operational issues to understand how our labels support this action) (volunteer with professional supervision);
    - collecting health assessment forms (volunteer); and
    - providing patient information sheets that explain the importance of complying with the drug regimen, the danger of overmedicating, and the date to return for the next regimen (volunteer with professional supervision).
- Provide physical security for traffic and crowd control and protection of SNS, equipment, and materiel (law enforcement)
- Manage dispensing-site operations and serve as the problem solver of last resort (local public health staff)

6.2 Dispensing Oral Medications

In order to comply with current state regulations regarding dispensing medication, the plan must have a policy and SOP of who will dispense medications, and how the medications will be dispensed (attachment 3, CSR 150-5.100). Local SNS teams will not be responsible to repackage bulk medication; all medication will come prepackaged in either unit-of use bottles or in a prepackaged bag. Medication will be packaged for a ten-day treatment regiment (20 pills per bottle/bag).

The following guidelines must be followed when dispensing medications (reference Public Health Nursing (PHN) Manual, Section 200, Subsection: 200.70, 9/98):

- Definitions:

    - Dispense: The act of dispensing includes the selection and labeling of prepackaged medications ordered by the physician or advanced practice nurse to be self administered by the client (individual presenting at dispensing clinic). Only a physician, pharmacist, or a registered nurse may dispense medications.

    - Administer: The act of administering medication involves giving the client a single dose of prescribed medication. All personnel who are licensed to do so may administer medications.

    - Nursing Protocol: Describes the steps to be taken in the nursing management of specific health problems. Includes strategies for obtaining historical and physician assessment data and plans of action. Nursing protocols do not need to be signed by a physician.

    - Drug Order or Prescription: A physician has the independent legal authority to administer or dispense drugs. This authority is delegated to another person through an order, prescription, standing orders, protocols, or collaborative practice agreement. An order is generally considered to be written on the client's

record. A prescription generally refers to an order written on a separate piece of paper. For simplicity, the word "order" will be used throughout this document.

- Medical Protocol: Describes the medical treatment to be included in the plan of care for a specific condition. This includes prescription medications and treatments that require a physician's signed order.

- Standing Order: Often used interchangeably with the term "medical protocol." A standing order is usually narrower in focus and consists of physician orders only (i.e., Immunization Standing Order).

- Collaborative Practice Agreement: A written agreement that states jointly agreed-upon protocols or written standing orders for the delivery of health care services.

- Responsibilities of the RN Related to Dispensing Medications

1. Obtain Order and/or Medical Protocol – Physician order to treat individuals for biological and chemical agents during a mass prophylaxis event must be signed by a local physician. Physician's orders and/or protocols must be rewritten or reviewed, signed and dated at least yearly or more often if indicated.

    - Protocol or Standing Orders should include: (from the DHSS Public Health Nursing Manual, Section 200.70 Professional Practice Framework, page 2 of 6, 9/98)
        1) Medical order for the medication;
        2) Name of the medication;
        3) Strength of medication (as per age, weight, condition, etc.);
        4) Frequency medication is to be taken (as per condition, etc.);
        5) Exact dosage (as per age, weight, condition, etc.);
        6) Quantity of medication;
        7) Method of administration (as per age or condition, etc.);
        8) Permission to refill;
        9) Condition for which the medication would be dispensed. Example: for client who has been exposed, or exposure is suspected, to a biological agent;
        10) Signatures of physician(s) and registered nurse(s) implementing the protocol; and
        11) Date signed.

    - The DHSS recommends that standing orders and/or medical protocol include: (from the DHSS Communicable Disease Investigation Reference Manual, Guidelines for Physician Orders, Chapter 1, page 17, 9-28-99)
        1) The geographic area to be served by the public health agency (for instance the area in which dispensing sites will be located, SY County or YZ City);

2) Process for the review of services by the physician and nurse (evaluation of the standing orders protocols and implementation should be on a predetermined time schedule. The scope of the evaluation will vary widely dependent upon the services to be provided. The scope should include evaluation of current treatment recommendations for the agents as stated on the CDC website;
3) Full name of the group of individuals who will receive treatment such as, "persons presenting themselves for prophylaxis treatment for a biological or chemical event";
4) Date the order is written by the physician;
5) The name of the medication to be dispensed or administered;
6) Dosage of the drug or reference to established guidelines such as those from the CDC or other expert professional groups;
7) Method of administration of medication; and
8) Signature of physician.

- Recommendations for physician order and/or medical protocol:
    1) Discuss treatment protocol for biological and chemical agents with physician and alternate physician (DO THIS NOW. DO NOT WAIT FOR AN EVENT);
    2) Discuss collaborative agreement, standing order, and/or medical protocol with the physician and alternate physician, this should be between the physician and the registered nurse who will be considered the nursing supervisor during the event (see attachment 5 & 6);
    3) Discuss professional health care workers licensed in another state who may volunteer (see attachment 7-1 and 7-2);
    4) Discuss health assessment form with physician (see attachment 8);
    5) Include Investigational New Drug procedures in orders (see number 3, label medications for list of IND medications);
    6) Include specific treatment of individuals that have contraindications to antibiotics included in the SNS;
    7) Prior to the event, identify registered nurses and/or pharmacists who will be dispensing medication under the physician order, attach a copy of each person's professional license to the protocol, this may be a license to practice in another state;
    8) If the physician chooses to not sign the order until an event occurs, assure that all issues have been discussed with the physician and alternate physician, and have the order developed so that signature can be obtained without a time delay;
    9) Have a backup physician willing to sign the order in case primary physician is unavailable during the event; and
    10) A copy of the signed medical protocol and/or order should be available at each dispensing site while the site is in operation. The original should be kept at the LPHA.

A reference CD developed by Dr. Robert Hamm is available upon request by calling the CERT at 573-526-4768 and request Biological/Chemical/Nuclear Terrorism Manuals & Handbooks, Information for Clinicians. Upon request a CD can be mailed directly to a local physician.

*Local Public Health Agencies requiring direct assistance in developing or implementing orders and/or medical protocols should call the CERT at 573-526-4768 to ask for assistance.*

*A suggested template for standing orders for mass prophylaxis for biological agents will be developed by CERT and provided to the LPHAs by December 2003.*

2. Assess Individuals Presenting for Prophylaxis – Verify that each individual who receives medication has completed the health assessment form and that the form has been reviewed to determine the appropriate antibiotic regime.

    - Assess the individual's condition including:
        1) Need for medication; and
        2) Contraindications i.e., allergic reactions, pregnancy, breastfeeding, etc.;

    - For refills assess:
        1. Signs and symptoms of side effects; and
        2. Compliance with treatment.

    - Verify presence of a current, complete, signed physician's order and/or protocol in the agency.

    - Medication should NOT be provided if in the registered nurse's judgment:
        1) The individual's condition contraindicates further medication until the nurse has conferred with the physician;
        2) The individual's ability to be responsible for a quantity of medication is highly questionable (for example individuals who may not understand the treatment regiment). The physician should be consulted;
        3) The medication is outdated, obviously contaminated or otherwise compromised; or
        4) The medication has not been stored properly.

3. Label Medication – State and federal regulations specify the information that must be provided on the drug label and the patient information sheet that must be given to the public when dispensing prophylactic medicines.

    CSR 150-5.020 and 4 CSR 200-4.200 (see attachment 5 & 6) outlines the requirements for labeling of all medications.

- The label must contain:
    1) Date medication dispensed;
    2) Sequential number;
    3) Individual's name;
    4) Prescriber's direction for usage including frequency and route of administration;
    5) Prescriber's name;
    6) Name and address of the agency dispensing;
    7) Name and strength of the drug dispensed;
    8) Quantity dispensed; and
    9) Number of times refillable, if appropriate, or the words "no refill".

- The SNS Program has designed the drug labels to facilitate the manual capture of drug, lot, and recipient information:
    1) Unit-of-use bottles have two tabs on their side. Each tab contains the drug name, expiration date, lot number, and a unique prescription number. By affixing one of the tabs to a recipient's health assessment form, the drug and its lot that each recipient receives will be recorded. If the person who dispenses the drug further annotates the form with their identification, date, time, and location, where, when, and how a recipient received the drug can be tracked.
    *Labels on the unit-of-use bottles that the SNS Program vendor prepares will have only the drug name, strength, quantity, lot number, and unique prescription number. The dispensing sites must provide the above information plus a 24-hour telephone number to call with questions.*

    2) Packaging machine labels have a tear-off tab on the bottom of the label that contains the same unique prescription number as the label itself. If this tab is torn off and stapled to the recipient's health assessment form, there will be a link between a drug, its lot, and its recipient.

    3) CD-printed labels do not have a tab but dispensing could stamp a unique prescription number on the health assessment form and the drug label. To accomplish that, 30 number-stamping machines are supplied in each 12-hour Push Package. The machines are hand-held imprinters that will stamp a 7-digit number the number of times that you specify. For example, the machine can be set to increment its number after stamping the number twice. That would allow the health assessment form and the drug label to be stamped with the same number before the stamping machine incremented its number. By assigning persons who hand out drugs at a dispensing site a block of numbers for their stamping machines, management will know the recipients that got specific drugs, at a specific dispensing site, from a specific person.

4) The SNS Program will stock preprinted labels as part of the 12-hour Push Package. Since it is not known where the Push Package will be sent, only the drug name and directions/cautionary statements will be put on the label, the additional information would have to be added at the time of an event.

5) The CDC has supplied each state with a CD titled *Post-Exposure Prophylaxis for Anthrax, Plague, and Tularemia: Patient Drug Information Sheets and Dosing Instruction Labels in 48 Languages*. When the software is used to create a label in a language other than English, the English version of the label will have to be edited and then two labels printed, the edited one in English and a second in another language. Apply the English label on the front of a regimen bag and the foreign language label on the rear (for repackaged stock only, see below for placement on bottles). The English version will contain FDA-required variable information such as prescribing agency, city and state, 24-hour number, prescriber, prescription number, prescription date, and number of tablets in the regimen. Labels in other languages only contain instructions for taking the drug and precautions for using it. You cannot edit the foreign language labels.
**Contact Angela Ford at forda@dhss.mo.gov to request a copy of the CD. There are no exemptions to these requirements for a label.**

6) The CD is designed to print labels on plain Avery® 5395 Name Badge Labels or its equivalent. This label was chosen for several reasons. It holds all required prescription information in English. Its font is readable, but unfortunately the label is too large to fit on the unit-of-use regimen bottles. Instead, affix it to the back of the patient information sheet that is given to individuals with their unit-of-use regimen.

7) Off label use of SNS Drugs – All of the drugs in the SNS have long-established safety and efficacy records. However, some are not FDA-labeled to treat specific agents released by a terrorist. The SNS Program is working with the FDA to establish a streamlined process that will qualify these drugs to save the trouble of using them as investigational new drugs (IND).
**Currently, the following drugs in the SNS are considered investigational:**
   - Anthrax vaccine for anthrax post exposure prophylaxis
   - Amoxicillin for anthrax post exposure prophylaxis
   - Gentamicin for tularemia treatment
   - Gentamicin for plague treatment
   - Ciprofloxacin for tularemia post exposure prophylaxis
   - Ciprofloxacin for tularemia treatment

- Ciprofloxacin for plague post exposure prophylaxis
- Smallpox vaccine (Wyeth)
- ACAM 1000 smallpox vaccine
- ACAM 2000 smallpox vaccine
- Cidofovir for treatment of adverse reactions to smallpox vaccine

**Non-IND drugs in SNS (FDA-approved indications) include:**

- Anthrax vaccine for pre-exposure prophylaxis
- Ciprofloxacin for Anthrax treatment and post-exposure prophylaxis
- Doxycycline for Anthrax treatment and post-exposure prophylaxis
- Doxycyline for plague and tularemia treatment or post-exposure prophylaxis
- Botulinum antitoxin trivalent beepers A, B, E, for botulism

*State and Local Public Health Agencies do not need to develop IND forms, or incorporate IND signature information on the health assessment form. In the event of a BT incident, CDC will send consent/assent forms, information sheets, protocols/treatment guidelines, case report forms, adverse event reporting forms, and other specialty items. States will be required to let CDC know the languages needed for the forms.*

4. Document – State regulations (4-CSR 150.5.020, 4 CSR 200-4.200, attachment 5 & 6) outline the requirements that must be followed for dispensing medications. Records must be maintained to guarantee security, storage, and accountability.

   - Health assessment form:
     1) LPHAs must retain the health assessment form at their agency site (LPHAs will be informed after the event of what to do with the forms, in multi-county arrangements one LPHA can be designated to retain all forms).
     2) Each individual obtaining medication must have a completed health assessment form that is signed by the health professional that dispensed the medication and/or provided counseling.
     3) Individuals picking up medications for family members or other individuals not present must complete the health assessment form for each person receiving medication.
     4) Forms can be retained in a general file; individual files for each person do not need to be developed.
     5) Since one family member may pick up for the entire family, it is suggested that a family file be maintained.
     6) The physician order does not have to be attached or referenced on the health assessment form; by using the form it is understood that the individual received treatment under the mass prophylaxis medical protocol.

***ASSESSMENT FORMS: In order to have continuity of a statewide response to an event, health assessment forms are being developed by the CERT. The forms will be agent specific and are to be used in conjunction with the dispensing of any medication obtained through the SNS (see attachment 8). A template of each form will be sent to LPHAs by 12/03. It will be the responsibility of the LPHA to make copies and to provide forms to any medical provider that they distribute medication to from their SNS stock.***

If documentation is complete on the health assessment form, then given the possibility that large numbers of individuals will require prophylaxis, LPHAs will not be required to maintain a medication log. LPHAs will not be required to enter large numbers of individuals receiving mass prophylaxis into MOHASIC, the exception being individuals who receive a smallpox vaccination; these individuals must be entered into MOHASIC.

5. Provide Information to Drug Recipient(s).

   Local public health agencies and/or private health care providers will be required to make copies of all drug information sheets that will be distributed to individuals receiving prophylaxis. These can be copied from the CD provided by CDC, or from information obtained from the CDC website. The DHSS will also have the information located on the emergency response web page.

   - The following information must be given to, and discussed, with all individuals receiving prophylaxis:
     1) Conditions for which the medication has been prescribed;
     2) Explanation of the Investigational New Drug form (if required);
     3) Effects of medications, expected and untoward actions;
     4) How, when, what, and amount of medication to take;
     5) When to return for refill of medication;
     6) The 24/7 number to call if they experience side effects or become ill;
     7) Warning to keep the adult medication out of reach of children; and to not give children the adult medication;
     8) Explanation of why they may not be getting the same drug given to their family members, or a neighbor;
     9) The importance of taking the prescribed treatment for the full period prescribed; and
     10) Care of vaccination site (if smallpox vaccination).

6. Track Drugs and Drug Recipients– The key to tracking a drug, its lot, and its recipient is the drug's unique prescription number. Annotating that number on the patient's health assessment form will allow identification of every patient that received a particular drug/lot combination.

   - Tracking drugs and drug recipients is a process that:

1) Starts with the completion of an health assessment form for everyone who receives protective medicines, including those in line and those (children and family members who are ill, incapacitated, or did not come to the dispensing site) for whom people in line will pick up regimens; and
2) Records, on the health assessment form, the information about the drug that a person receives and information associated with dispensing it to them (date, time, location, dispenser, and especially the prescription number).

- Recording this information allows:
    1) Tracking possible contamination or adulteration of drug lots,
    2) Investigating serious adverse reactions (required by FDA) to investigational new drugs such as ciprofloxacin for tularemia or amoxicillin for anthrax,
    3) Identifying the failure of prophylaxis when individuals contract a disease in spite of having taken oral drugs to prevent it,
    4) Informing recipients of FDA drug recalls for additional or different drugs in the event of prophylaxis failure; and
    5) Identifying individuals who do not return for refills.

6.3 Command and Control Support for Dispensing Drugs

- Before dispensing can begin, the command and control function must provide definitive guidance on the following:
    1) Multiple versus individual regimens:
        - A multiple regimen policy allows an adult to pick up medicines for other individuals who are sick, incapacitated, or unable to come to the dispensing site. A multiple regimen policy potentially shortens dispensing lines, gets people their drugs faster, and reduces public frustration and the number of staff that must deal with it. It also allows some individuals to acquire more drugs than they should have, but its benefits far outweigh that possibility.
        - If multiple regimen pickups are allowed, the public health information campaign needs to tell the public specific information they need to bring to the dispensing site for individual not presenting at the dispensing site.
        - A health assessment form must be completed on each individual receiving medication. Therefore, individuals picking up for other family members must be able to complete the form.
        - In order to limit abuse, consider the type of evidence that should be brought to justify the number of regimens requested.

    2) Prophylactic regimens:

- Missouri will utilize the unit-of-use regimens provided by the SNS program for the treatment of various biological threats.
- The SNS Program supplies labeled, unit-of-use, 10-day regimens, which require no repackaging for dispensing.
- Missouri will only dispense a 10-day regiment at the first dispensing clinic; no dispensing site will receive enough antibiotics to dispense a full 60-day regiment at the first dispensing clinic.
- The SNS intentionally designed the regimens to begin prophylactic treatment for anthrax, the worst-case scenario recognizing that they contain 3 days more product than the treatment for plague but 4 days less than the treatment for tularemia. If the treatment is for tularemia, the SNS will provide additional 10-day regimens to complete a 14-day prophylaxis.

- Protecting Undocumented Aliens

  - Several counties have populations of undocumented aliens whom they must protect in an emergency. For these individuals, the fear of arrest and deportation may be greater than the fear of getting a disease from a terrorist attack. An effective campaign to convince undocumented aliens of the importance of taking their families to a dispensing site should be addressed in each community.

- Pediatric Prophylaxis

  - Each 12-hour Push Package contains quantities of the following:
    1) Ciprofloxacin oral suspension, which will provide 4,000 individuals 5 days of prophylaxis (Cipro suspension comes with its own diluent);
    2) Doxycycline oral suspension (LPHAs must have a supply of distilled water to dilute, 25mg/ml, 60ml mfg. bottle; distilled water is not provided through the SNS or from the state distribution site); and
    *3)* Doxycycline pediatric syrup for the treatment of children and adults who have trouble swallowing tablets. Doxycycline pediatric syrup will provide 7 days. The last is adequate for protecting against plague, but insufficient for a 14-day course against tularemia or a 60-day course against anthrax.

    *Additional pediatric medication will be obtained from the Vendor Managed Inventory (VMI) if supplies are exhausted from the 12-hour push package See attachment 9 for preparing oral suspension of Ciprofloxacin and Doxycycline.*

  - Because limited amounts of the above are kept on the 12-hour push package, Missouri will use the following*:*
    1) The Push Package's 25,000 10-day regimens of amoxicillin chewable tablets. These are in the Push Package primarily to protect pregnant women, people who are allergic to ciprofloxacin and doxycycline, and children against

anthrax. Children between the ages of 2 to 5 can chew these tablets. Younger children will readily take them if you crush and mix them in a food such as applesauce. The softness of the tablet and a groove down its middle make it easy to divide into the smaller portions dictated by the child's weight. (The main drawback to any use of amoxicillin for anthrax is that it is not a labeled use. It must be administered as an investigational new drug.)

2) Converting ciprofloxacin and doxycycline tablets into oral suspension. While all pharmacists learn how to compound drugs, few do it frequently enough to be proficient. However, many communities have a small number of pharmacies that specialize in compounding. These pharmacies may be identified by looking in the Yellow Pages® or by contacting Missouri's State Board of Pharmacy. The SNS Program suggests that contingency contracts be established with these local pharmacies to increase the ability to protect more individuals with oral suspensions during a terrorist event.

- Special Populations; Protection of Those Who Cannot Use Dispensing Sites:

  - Every community will have groups of people who will not be able to use dispensing sites:
    1) Inmates of a corrections system (jails, prisons, juvenile detention facilities)
    2) Patients in nursing homes and other long-term care institutions
    3) Patients in hospitals for reasons not related to the terrorist threat
    4) Immobile patients who get care at home through local home healthcare service providers

Plans need to identify methods for providing prophylactic medicines to these individuals. Fortunately, many of them receive medical care from some type of healthcare facility. It is recommended that the facilities be identified and the plan state how medications will be dispensed in the facility to assure prophylaxis to the individuals they serve. If a facility utilizes medications from the SNS, each individual receiving medication must have a health assessment form completed and receive drug information sheets.

## Chapter 6 summary: At a minimum, the plan should include:

- **a detailed description of the operational plan; including policies and procedures of the components listed above regarding RN responsibilities when dispensing medications;**
- **a definition of roles and responsibilities for staff and volunteers;**
- **a signed physician order and/or medical protocol for mass prophylaxis for a biological and/or chemical event, or;**
- **documentation of discussion with named local physician and alternate physician(s) who is willing to sign the orders if an event occurs;**
- **description of how dispensing sites will function; and**

- **description of how undocumented aliens and individuals unable to physically come to the dispensing site will be reached.**

## CHAPTER 7: COMMUNICATION

During a large-scale emergency, public fear and anxiety may impair the ability to dispense prophylaxis to those who really need it. An effective health communications plan that informs and reassures the public will reduce fear and anxiety and will be crucial to earning public confidence and cooperation.

When writing the dispensing section of the SNS plan, it is imperative that the health communications plan within a all-hazards or bioterrorism response plan contains comprehensive, accurate, reassuring information about the threat; dispensing efforts to protect the potentially exposed; and treatment efforts to care for the sick.

To create an effective heath communications plan, start long before an emergency to work with health professionals, the media, and other groups to prepare multi-language messages and information that are a threat and incident specific. Threat-specific messages tell people specific information about the disease, the protective drug regimens that the local government will provide to protect them, and the routine that they should expect when they go to a dispensing site. Incident-specific messages tell people who are potentially exposed where they must go for prophylactic medications if they are well, and where they need to go if they are sick.
An effective health communications plan will have messages and information materiels prepared before an emergency so that authorities can quickly add incident-specific data at the onset of an emergency.

7.1 When completed the health communications plan should include the following:

1. Basic Medical Information About the Event That Has Occurred:
   - Agent involved
   - Early signs and symptoms, including information on incubation period
   - Mode of transmission
   - Community locations affected by the agent
   - Asymptomatic persons will have time to get treated and should avoid going to local hospitals
   - Symptomatic or ill persons should consult with their health care providers

2. Information about public dispensing sites:
   - Locations and hours of operation of open Dispensing Sites in the affected community
   - Eligibility criteria to receive prophylaxis: "If you don't fit the criteria, you do not need treatment"
   - Basic message: "Go to the Dispensing Site assigned for your residence location or as directed"
   - Information they need to bring to the Dispensing Site
   - Information phone hot-line number to provide information about the event, agents, Dispensing Sites, etc.

**3.** What to Expect at Dispensing Sites and Information Regarding the Medications:

- Shots, pills or both? Description of medication(s)/vaccine.
- Local supplies of the needed medication have been exhausted (don't contact your local pharmacy for the medication).
- The Strategic National Stockpile has been requested for the community
- It is important to reinforce to the public that regimens may change as more is learned about the specific threat. Information that pills may vary in numbers and colors due to the manufacturing difference relating to dosage and vendors.
- Wait may be long. Please be patient.
- Persons over 16 years of age will be asked for a picture ID, or other means of identification. Adults will have to give written consent for minors and accompany them.
- Adults will be able to obtain additional antibiotic treatments for other household members, including disabled, homebound relatives, or neighbors. In addition to their own picture ID, adults must provide identification, health information, drug allergies, and current medication lists for each person for whom they wish to obtain prophylaxis. Medication may be obtained for others if in pill form; if vaccinations are required each person must be at the Dispensing Site in person.
- Each Dispensing Site will have a general flow and everyone will be treated in an orderly fashion, which is set up by the Dispensing Site management.

4. Worst Case Scenarios Requiring Antibiotic Prophylaxis to over 100,000:

- One adult representative from each household can receive medications for the entire household:
- List of acceptable documents for other household members (e.g. driver's license, tax return, social security card, etc.).
- For children <13 years old: current weight, age, health information, drug allergies, and current medication lists will be needed.
- For adults: health information, drug allergies, and current medications list.

**5.** Legal Issues:

- Don't cheat. Persons caught hoarding or reselling pharmaceuticals intended for mass prophylaxis will be prosecuted.
- Do not use any pharmaceuticals obtained through unofficial sources, they may be ineffective or harmful. Use only medications provided at the Dispensing Sites or prescribed by physicians and dispensed by a licensed pharmacist.

**6.** Other Information:

- Do not use out-dated medications.
- Medications are free.
- If you are unable to get to a Dispensing Site and are indicated to get the medication, notify the appropriate authorities (give number to call).
- If someone wants to volunteer, give information on were they could respond.
- If someone wants to make donations, give information on how to accomplish this action.

- Other information as needed.

## Chapter 7 summary: At a minimum, the plan should include:

- **how the public will be informed about the threat;**
- **multi-language messages;**
- **how the public will be informed about the location of the dispensing sites;**
- **what messages will be provided to the public to decrease fear; and**
- **agreements with local media regarding their role in a public health event.**

## CHAPTER 8: PREPARE, TRAIN, EXERCISE, AND EVALUATE

Previous chapters have discussed the components of the local plan for dispensing the Strategic National Stockpile (SNS) during a terrorist attack, natural disaster, or technological accident. This chapter discusses what the community needs to do after the plan has been created. To be confident that the plan will result in the effective and rapid distribution of the SNS, communities need to do the following:

- Confirm/solidify preparations by ensuring that the human resources, support organizations/agencies, partners, and facilities that are included in the plan will be there when needed. This can be assured by establishing memorandums of understanding, contingency contracts, and other agreements. A detailed checklist is included in Attachment 10. Use this list to assure that essential details, actions, and agreements have not been overlooked.
- Train for each of the functions in the plan so that everyone knows their job and how to work together.
- Exercise all components of the plan by simulating probable emergencies to validate its effectiveness.
- Evaluate exercises to identify where to improve the plan.

## 8.1 Confirm and Solidify Preparations in the Plan

Once the plan is created, in order to ensure that the human resources, support organizations/agencies, partners, and facilities identified in the plan will be available during an emergency, the following actions are suggested:

- Human resources
  - Identify permanent, borrowed, and volunteer staff;
  - Recruit and hire permanent staff and establish agreements for borrowed and volunteer staff;
  - Develop organizational charts, job descriptions, checklists, and other personnel-related materiel to help the local SNS team members remember important aspects of their jobs and their relationships within the chain of command; and
  - Develop activation and call-down systems that have redundant means of notifying local SNS team members.
- Support organization/agencies
  - Negotiate and obtain memorandums of agreement or letters of commitment from organizations; law enforcement and other security providers; local departments of transportation, public works, emergency management, health, and other agencies that will provide support.
- Partners
  - Negotiate and award contracts with private partners for transportation, security, lodging, food, drink, and other amenities; and
  - Develop agreements with civic groups, and fraternal organizations for personnel and equipment support.
- Facilities

- Obtain letters of commitment from facility management for use of dispensing sites; and
- Establish contingency contracts for private for-profit facilities.

8.2 Train

The purpose of training is to make sure that individuals know how to do their jobs, that they know how to work with others in their functional group, and that functional groups know how to work together. These goals can be accomplished by using a variety of methods, including videos, written training manuals, classroom instruction, and on-the-job training. The SNS video is particularly helpful for acquainting the local SNS team members with the SNS.
*To schedule training utilizing the SNS video, contact a state regional planner, or contact the CERT.*

- Functional Group Training

  The goal of this training is to teach individuals how to work as members of an SNS team and to how to work smoothly together to get the SNS materiel to those who need it during an emergency.

  This training initially emphasizes the process, flow, and expectations of each functional area. Once a functional group works smoothly together, the training should bring all functional groups together for SNS system-wide training so that individuals understand the entire SNS operational process. Group training should ensure that
  - All team members can function in their assigned jobs;
  - Functional group members understand how their job supports their functional area;
  - Functional teams are familiar with their work location, facilities, equipment, and function leadership;
  - All functional groups understand how they integrate into the overall SNS operational plan; and
  - Everyone understands how to work safely.

*The CERT and the Federal SNS Program staff will provide functional training sessions statewide in 2004.*

- Orientation Training

  At a minimum, the audience for orientation training should include the following:
  - Local leaders;
  - Local emergency planners;
  - Members of the local EOC or command and control structure;

- Essential emergency response personnel, including first responders and personnel from the medical infrastructure (hospitals, health clinics, professional associations);
- All local SNS team members; and
- Public information and/or health education specialists.

It is also important that this training be available to private-sector firms and local organizations that will support various activities in a community plan. It is important that they understand how they fit into the larger picture of the local SNS response.

It is suggested that the following be covered in local SNS orientation training:

- How and why the state/community will request the SNS;
- How the SNS will arrive;
- What materiel, equipment, and technical assistance will come with the SNS;
- How the functions in the local plan will dispense medication to the population; and
- How the local SNS plan integrates into the broader local all hazards or bioterrorism response plan.

- Individual Training

  This training makes sure that individuals understand and can perform the tasks that the plan assigns, as well as work with others in their functional group. Some of the SNS team members will be functioning in the same duties that they routinely perform, such as pharmacists, social workers, nurses, and truck drivers. Others such as civic and fraternal group members who staff positions in dispensing sites, will need basic familiarization and specific task training before they can perform effectively. Everyone who is part of your local SNS team needs to understand what he or she must do when the team activates. These activities include actions such as
  - Where to get prophylactic medicines for essential personnel protection,
  - Where to get proper credentials, and
  - Where and when to report for duty.

8.3 Operational Exercises

Operational exercises test likely responses to probable events—chemical, blast, or biological (contagious and non-contagious agents). Such exercises are valuable because they enable communities the ability to evaluate how well the plan works and identify where it needs improvement. Some exercises may test only limited parts of the plan such as the activation of the recall roster of SNS functional group participants. Other exercises will be considerably more comprehensive and include an all hazards/bioterrorism response plan event command and control function, as well as the physical receipt and dispensing of the SNS training package.

- Planning Group
  To plan exercises that adequately evaluate the readiness of the communities plan to respond to an emergency, we suggest that you establish a planning group comprising
  - Fire department personnel;
  - Law enforcement personnel;
  - Personnel from local hazardous response teams;
  - Health department personnel;
  - Local healthcare professionals and hospital administrators;
  - Representatives from state and local emergency management agencies;
  - Leaders of the Metropolitan Medical Response System (MMRS), if you have an MMRS in your local area; and
  - Public information and health education specialists.

8.4 Evaluation of Plan

Evaluation of an exercise (or a real event) assesses whether the plan and training accomplished its objectives and, to the degree it fell short, where improvements are needed based on lessons learned.

- Purpose of any exercise is to
  - Evaluate individual competence, the effective operation of a functional group, and the smooth interaction of all functional groups to deliver the SNS;
  - Evaluate the accuracy, completeness, and quality of your SNS plan; and
  - Recognize areas that need improvement.

- Evaluation
  As exercises or responses to real events are evaluated, the following questions should be answered:
  - Did the participants have the knowledge and skills that training was supposed to provide?
  - Did the participants use those knowledge and skills properly?
  - Did their knowledge and skills meet organizational objectives?
  - Was the plan accurate, effective, and current?
  - What were the lessons learned from the exercise/event and how should those lessons change the local SNS plan to make it better?

- Collection of Data
  After an exercise or an actual emergency, it will be important to reconstruct what, when, and why events happened to improve the plan and future response. Three actions that will greatly facilitate that process:
  - Maintain comprehensive command and control logs. The command and control function should log the date and time of events as they occur to provide a basic chronology of the emergency that includes, for example, the first reported case of a threat, request for the SNS, arrival of the SNS,

activation of specific dispensing and treatment locations, and hospital reports of casualties.

- Place date and time on all SNS operational support forms. Forms—such as orders for SNS materiel by treatment centers and dispensing locations, issues related to inventory control function, and deliveries to dispensing and treatment locations—should contain dates and times so that the action can be integrated into the chronology of an emergency and draw conclusions about the level of service provided.
- Ensure all SNS situation reports contain date and time references. Situation reports from each SNS function to the SNS operations management function identify problems and provide quantitative operational indicators, local SNS team managers will use situation reports to manage the local distribution to dispensing sites of the SNS materiel. After an emergency, the time and date of each report will allow the reconstruction of the events during the emergency and the community's response to it.

## Chapter 8 summary: At a minimum, the plan should include:

- **detailed lists of personnel and contacts for support organization/agency, partnerships, and facilities that support the local SNS plan to make sure all required resources are available to respond;**
- **a process to conduct SNS orientation and individual/functional group training; and**
- **a process for exercising and evaluating the plan.**

***For assistance with all aspects of the local SNS response plan, contact the Center for Emergency Response and Terrorism (CERT), Department of Health and Senior Services (DHSS) at 573-526-4768.***

## Attachment 1

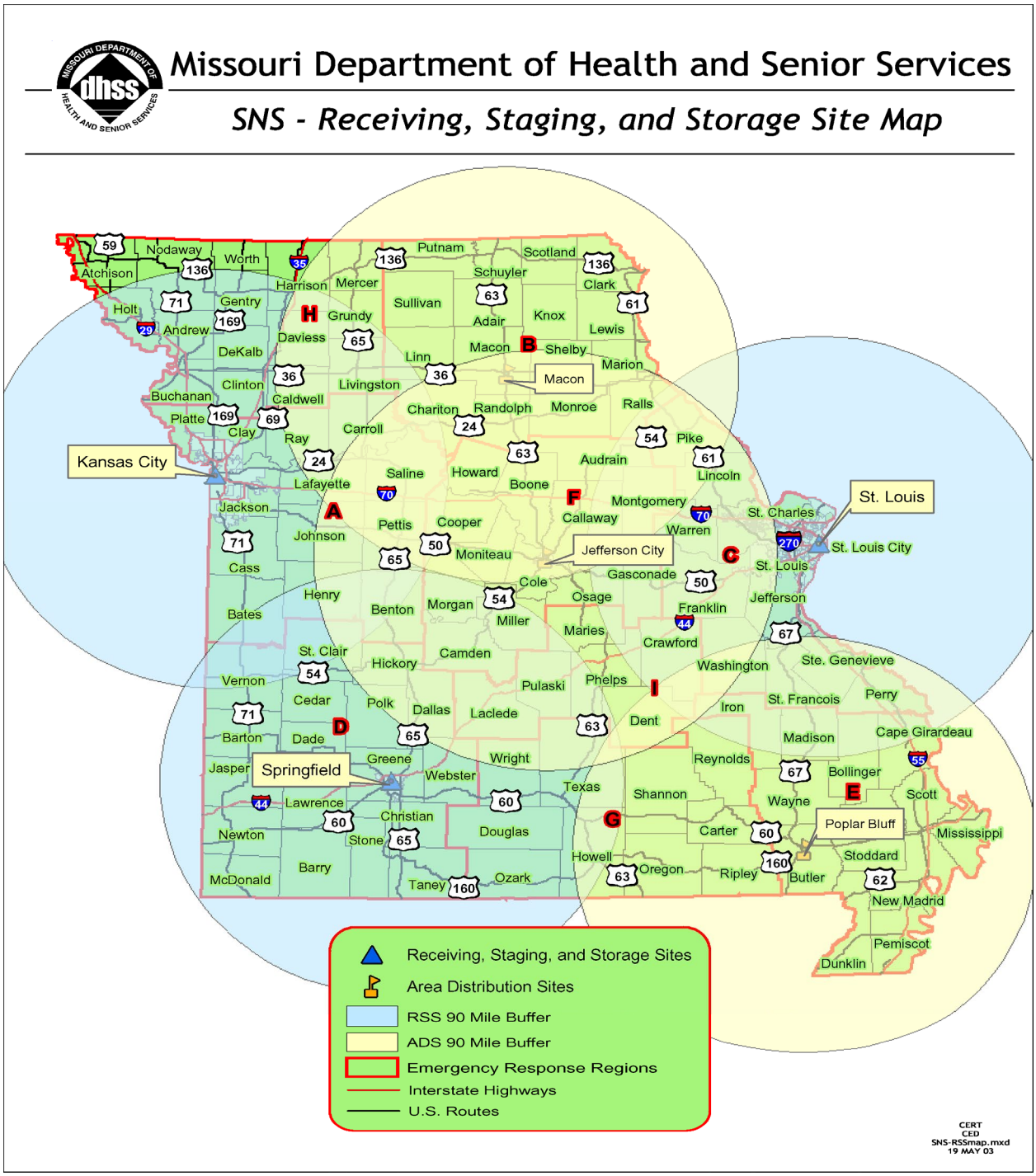
# Missouri Department of Health and Senior Services
# Strategic National Stockpile Program
# Materiel Transfer Form

The Department of Health and Senior Services National Pharmaceutical Stockpile Program hereby transfers medical materiel from the National Pharmaceutical Stockpile into the custody and control of the receiving authority listed below. By signing this form, the receiving authority acknowledges receipt of the medical materiel listed on the accompanying manifest.

The receiving authority accepts full responsibility for the materials entrusted into its possession and agrees to abide by the terms, conditions, and responsibilities, of all applicable federal and state laws and regulations. The receiving authority accepts full responsibility for ensuring the proper training of administrators of Mark-1 chemical antidote auto injectors as well as diazepam auto injectors (if transferred).

| | |
|---|---|
| DHSS National Pharmaceutical Stockpile Authority<br>(PRINT NAME & TITLE) | SIGNATURE & DATE |
| Authorized Receiving Authority<br>(PRINT NAME & TITLE) | SIGNATURE & DATE |
| (If Control Schedule II Substances are Transferred) Authorized Receiving Authority DEA Registrant<br>(PRINT NAME, TITLE, & DEA REGISTRATION NUMBER) | SIGNATURE & DATE |

# Attachment 2



# Attachment 3

BUREAU OF NARCOTICS AND DANGEROUS DRUGS (BNDD)
REGULATIONS for CONTROLLED SUBSTANCES

19 CSR 30-1.031 Physical Security Requirements.
(1) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Department of Health shall use the security requirement set forth in 19 CSR 30-1.032–19 CSR 30-1.034 as standards for the physical security controls and operating procedures necessary to prevent diversion. Substantial compliance with these standards may be deemed sufficient by the Department of Health after evaluation of the overall security system and needs of the applicant or registrant.
(2) Physical security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operations. If a controlled substance is transferred to a different schedule, or a noncontrolled substance is listed on any schedule, or the quantity of controlled substances in the possession of the registrant in normal business operations significantly increases, physical security controls shall be expanded and extended accordingly.
(3) All registrants who receive or transfer substantial quantities of controlled substances in normal business operations shall employ security procedures to guard against in-transit losses.

19 CSR 30-1.032 Security for Nonpractitioners
(1) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the federal Drug Enforcement Administration (DEA) or with the Department of Health to determine that the person is registered to possess the controlled substance.
(2) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Department of Health of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency.
(3) The registrant shall notify the Department of Health of any theft or significant loss of any controlled substances upon discovery of this theft or loss.
(A) The registrant shall complete and submit a Report of Loss, Theft or Diversion of Controlled Substances or Regulated Chemicals to the Department of Health no later than seven business days after the discovery of such a loss. If the extent of the loss cannot be fully determined in that time frame, the registrant shall contact the Department of Health to request permission to submit an interim report and arrange for a complete report to be completed and submitted. The registrant may attach a copy of a completed Drug

Enforcement Administration Loss Form in lieu of completing the back or second page of a Report of Loss, Theft or Diversion of Controlled Substances or Regulated Chemicals form. In the event of theft, diversion or suspected theft or diversion, the report submitted to the Department of Health shall be accompanied by or followed by a summary of the internal investigation performed, the outcome of the investigation, and a copy of any law enforcement agency report completed if applicable.
(B) If an insignificant amount of a controlled substance is lost during lawful activities authorized under Chapter 195, RSMo, the reason for the loss or a description of what occurred, the name of the drug and the amount lost shall be documented in writing, signed by the registrant and attached or filed with the last completed annual inventory.
(4) The registrant shall not distribute any controlled substance as a complimentary sample to any potential or current customer without the prior written request of the customer, to be used only for satisfying the legitimate medical needs of patients of the customer and only in reasonable quantities. The request must contain the name, address and registration number of the customer and the name of the specific controlled substance desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition, the requirements for order forms shall be complied with for any distribution of a controlled substance listed in Schedule I or II.

19 CSR 30-1.034 Security for Practitioners
(1) Physical Security.
(A) Controlled substances listed in Schedules I and II shall be stored in a securely locked, substantially constructed cabinet.
(B) Controlled substances listed in Schedules III, IV and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies may disperse these substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.
(C) This rule also shall apply to nonpractitioners authorized to conduct research or chemical analysis under another registration.
(2) Other Security.
(A) The registrant shall not employ as an agent or employee who has access to controlled substances any person who has been found guilty or entered a plea of guilty or nolo contendere in a criminal prosecution under the laws of any state or of the United States for any offense related to controlled substances or who has had an application for a state or federal controlled substance registration denied or has had his/her registration revoked or surrendered for cause at any time. For purposes of this subsection, the term for cause means a surrender in place of or as a consequence of any federal or state administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances.
1. A registrant may apply in writing to the Department of Health and Senior Services for a waiver of subsection (2)(A) of this rule for a specific employee.
2. The Department of Health and Senior Services may issue a written waiver to any registrant upon determination that a waiver would be consistent with the public health and safety. In making this determination, the Department of Health and Senior Services shall consider—the

duties of the employee, the circumstances surrounding the conviction, the length of time since the conviction was entered, whether a waiver has been granted by the federal Drug Enforcement Administration (DEA) pursuant to 21 CFR 1301.76, the security measures taken by the employer to prevent the theft and diversion of controlled substances, and any other factors consistent with public health and safety.

(B) A registrant shall notify the Department of Health and Senior Services of the theft, diversion or significant loss of any controlled substances or regulated chemicals upon discovery.

1. The registrant shall complete and submit a report of the loss or diversion of controlled substances to the Department of Health and Senior Services no later than seven business days after the discovery of such a loss. The loss report form shall contain the following information; name and address of registrant, business phone number; Missouri Controlled Substance Registration Number; federal Drug Enforcement Administration Registration number; date of theft or loss; date of discovery of theft or loss; county of location; principal type of registration such as M.D., D.O., D.P.M., O.D., D.V.M., D.D.S., D.M.D., A.N.P., emergency medical service, pharmacy, hospital, manufacturer, nursing home kit, narcotic treatment program, teaching institution, distributor, importer, exporter, or other specified business; whether or not the loss or theft was reported to law enforcement; the name and phone number of the law enforcement agency reported to; the number of losses or thefts the registrant has experienced in the past 24 months; the type of loss or diversion such as, break in/burglary, robbery, employee theft, forged or falsified records, lost in transit, or other explained type of loss; if lost in transit, the name of the common carrier and name of consignee; the name(s) of the individual diverting controlled substances who was responsible for the theft or loss; copy of registrant's internal investigative report involving the loss or theft; the full name, date of birth and social security number of the individual(s) responsible for the theft or diversion, if known; a copy of the police report if law enforcement was notified; if the loss or diversion was in transit, identify the origin of the delivery, the name of the carrier(s) used and the name of the consignee; a list of all controlled substances lost, stolen or diverted by their generic name, trade name, the dosage strength, dosage form and quantity; the signature of the person completing the loss report and their title and the date of their signature. If the extent of the loss cannot be fully determined in that time frame, the registrant shall contact the Department of Health and Senior Services to request permission to submit an interim report and arrange for a complete report to be completed and submitted. The registrant may attach a copy of a completed Drug Enforcement Administration Loss Form in lieu of completing the back or second page of a loss report form provided by the Department of Health and Senior Services. In the event of theft, diversion or suspected theft or diversion, the report submitted to the Department of Health and Senior Services shall be accompanied by or followed by a summary of the internal investigation performed, the outcome of the investigation, and a copy of any law enforcement agency report completed if applicable.

2. If an insignificant amount of a controlled substance is lost during lawful activities authorized under Chapter 195, RSMo, the reason for the loss or a description of what occurred, the name of the drug and the amount lost shall be documented in writing, signed by the registrant and attached or filed with the last completed annual inventory.

Attachment 4

# DEA REGULATION
# 21 CFR 1301.75

**Section 1301.75 Physical security controls for practitioners.**

(a) Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.

(b) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

(c) This section shall also apply to nonpractitioners authorized to conduct research or chemical analysis under another registration.

(d) Carfentanil etorphine hydrochloride and diprenorphine shall be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container.

[39 FR 3674, Jan. 29, 1974, as amended at 39 FR 17838, May 21, 1974; 54 FR 33674, Aug. 16, 1989; 62 FR 13957, Mar. 24, 1997]

# Attachment 5

**CODE OF STATE REGULATIONS 1 MATT BLUNT (5/31/03)**
**Secretary of State**

# Rules of Department of Economic Development

## Division 150

## State Board of Registration for the Healing Arts

## Chapter 5 General Rules

### Title Page

**4 CSR 150-5.010 Amphetamine, Amphetamine-Like Drugs**
**4 CSR 150-5.020 Nonpharmacy Dispensing**
**4 CSR 150-5.030 Physical Therapy, Rehabilitation Services, or Both**
**4 CSR 150-5.100 Collaborative Practice**

**4 CSR 150-5.010 Amphetamine, Amphetamine-Like Drugs**

*Editor's Note: On April 14, 1992 the Circuit Court of St. Louis County found that 4 CSR 150-5.010 was void since it exceeded the statutory rulemaking authority granted to the Missouri State Board of Registration for the*
*Healing Arts in 334.125, RSMo.*

**4 CSR 150-5.020 Nonpharmacy Dispensing**

PURPOSE: This rule provides information concerning the general responsibilities of a physician who elects to dispense medications
from his/her office or clinic.

(1) Physicians must provide patients the freedom of choice concerning the source of drugs and devices prescribed during the course of
the physician/patient relationship. This means that no physician may require, as a condition of the physician/patient relationship, that the patient only receive drugs dispensed directly from the physician's office. By the same token, a physician cannot require any patient to use the services of any particular pharmacy.

(2) Physicians must provide appropriate, direct supervision to personnel employed to assist in the dispensing of drugs and devices from the physician's office. It shall be a violation of this rule for any physician to permit the dispensing of medication from his/her clinic or office when that physician is not present unless another physician duly licensed under the provisions of Chapter 334, RSMo is present.

(3) Physicians who elect to dispense medication must comply with the regulations governing the types of container that may be used to repackage prescription drugs as specified by federal law or rule unless the individual to
Who the drug is dispensed gives written authorization for the container to be otherwise.

(4) All drugs dispensed by a physician shall bear a label permanently affixed to the exterior of the drug container, which sets forth the following information:

(A) The date;

(B) The patient's name;
(C) Complete directions for usage;
(D) The physician's name and address; and
(E) The exact name and strength of the drug dispensed and, in the case of a generic drug, the name of the manufacturer or repackager of the drug. It shall be a violation of this rule for a physician to dispense a generic drug and affix to the label any trade name or other identification that would serve
to misrepresent the source of the drug.
(5) Physicians may dispense only to individuals with whom they have established a physician/patient relationship. It shall be a violation of this rule for a physician to dispense medication at the order of any other physician not registered to practice at that same location.
(6) It is not the intention of this rule to interfere with any recognized system for physician education operated by any accredited medical school located within the borders of Missouri nor is it the intention of this rule to interfere with the individual physician's appropriate use of professional samples nor is it the intention of this rule to interfere in any way with the physician's right to directly administer drugs or medicines to any patient.
(7) Whenever dispensing takes place, appropriate records shall be maintained. These records must be adequate to show the name of the patient, the name and strength of the drug dispensed, the quantity, the dose, etc. A separate log must be maintained for controlled substance dispensing.
*AUTHORITY: section 334.125, RSMo 1986. **
*Original rule filed May 11, 1984, effective*
*Sept. 14, 1984.*
***Original authority: 334.125, RSMo 1959.*

**4 CSR 150-5.030 Physical Therapy, Rehabilitation Services, or Both**

*PURPOSE: This rule provides information concerning the disclosure of a physician's pecuniary interest in a physical therapy or rehabilitation service as directed by section 334.100.2(21), RSMo.*

(1) Pursuant to the authority granted in section 334.100.2(21), RSMo, physicians who have a pecuniary interest in physical therapy or rehabilitation service facilities must disclose that interest to patients who are prescribed either physical therapy or rehabilitation services using the following form:
Missouri state aw, 334.100.2(21), RSMo, requires a physician notify the patient or guardian that the physician has a pecuniary (financial) interest in the physical therapy facility in which prescribed treatment is provided, and that physical therapy or rehabilitation services are available to the patient on a competitive basis from other facilities.
Therefore, I understand that Dr._____has a financial interest in_____ facility. Further, I understand that I have the right to choose any other physical therapy or rehabilitation services, which may be more convenient or competitive.

_____
Patient/Guardian Signature

_____
Date
This should be retained in the patient's permanent record.

AUTHORITY: sections 334.100.2(21), RSMo Supp. 1990 and 334.125, RSMo 1986. *
Original rule filed April 4, 1990, effective Nov. 30, 1990.
*Original authority: 334.100.2(21), RSMo 1939, amended 1945, 1959, 1963, 1974, 1976, 1979, 1981, 1983, 1984,1986, 1987, 1989, 1990 and 334.125, RSMo 1959.

**4 CSR 150-5.100 Collaborative Practice**
*PURPOSE: This rule defines collaborative practice arrangement terms and delimits geographic areas; methods of treatment; review of services; and drug/device dispensing or distribution pursuant to prescription*

*PUBLISHER.S NOTE: The secretary of state has determined that the publication of the entire text of the material, which is incorporated by reference as a portion of this rule, would be unduly cumbersome or expensive. Therefore, the material, which is so incorporated, is on file with the agency who filed this rule, and with the Office of the Secretary of*
*State. Any interested person may view this material at either agency's headquarters o the same will be made available at the Office of the Secretary of State at a cost not to exceed actual cost of copy reproduction. The*
*entire text of the rule is printed here. This note refers only to the incorporated by reference material.*
(1) For the purpose of these rules, the following definitions shall apply:
(A) Advanced practice nurse. A registered professional nurse who is also an advanced practice nurse as defined in section 335.016(2), RSMo;
(B) Collaborative practice arrangements refers to written agreements, jointly agreed upon protocols, or standing orders, all of which shall be in writing, for the delivery of health care services; and
(C) Registered professional nurse. A registered professional nurse as defined in section 335.016(9), RSMo, who is not an advanced practice nurse.
(2) Geographic Areas.
(A) The collaborating physician in a collaborative practice arrangement shall not be so geographically distanced from the collaborating registered professional nurse or advanced practice nurse as to create an impediment to effective collaboration in the delivery of health care services or the adequate review of those services.
(B) The use of a collaborative practice arrangement by an advanced practice nurse who provides health are services that include the diagnosis and initiation of treatment for acutely or chronically ill or injured persons shall be limited to practice locations where the collaborating physician, or other physician designated in the collaborative practice arrangement, is no further than fifty (50) miles by road, using the most direct route available, from the collaborating advanced practice nurse if the advanced practice nurse is practicing in federally designated health professional shortage areas (HPSAs). Otherwise, in non-HPSAs, the collaborating physician and collaborating advanced practice nurse shall practice within thirty- (30) miles by road of one another. The provision of the above-specified health care services pursuant to a collaborative practice arrangement shall be limited to only an advanced practice nurse.
(C) An advanced practice nurse who desires to enter into a collaborative practice arrangement to provide health care services that include the diagnosis and treatment of acutely or chronically ill

or injured persons at a location where the collaborating physician is not continuously present shall practice at the same location with the collaborating physician for a period of at least one (1) calendar month before the collaborating advanced practice nurse practices at a location where the collaborating physician is not present. The provision of the above-specified health care services pursuant to a collaborative practice arrangement shall be limited to only an advanced practice nurse. This provision applies to all collaborative practice arrangements between a physician and an advanced practice nurse unless a waiver is obtained as provided in 4 CSR 150-5.100(2)(D).
(D) If an advanced practice nurse has been continuously providing health care services pursuant to a collaborative practice arrangement with the same physician for at least one (1) year and the collaborating physician terminates the collaborative practice arrangement with less than thirty (30) days notice for reasons unrelated to the advanced practice nurse, 4 CSR 150-5.100(2)(C) may be waived by the board of nursing and the board of healing arts if the requirement for one (1) calendar month same-site collaboration would result in health care services at the location where the advanced practice nurse practices being discontinued or reduced. The request for the waiver with supporting documentation shall be submitted to the board of nursing or the board of healing arts by the advanced practice nurse or the collaborating physician and shall specify all information board of healing arts to evaluate the request including, but not limited to, the date and reasons for the termination of the collaborative practice arrangement, number of patients affected and plan for a new collaborative practice arrangement.
(3) Methods of Treatment.
(A) The methods of treatment and the authority to administer, dispense, or prescribe drugs delegated in a collaborative practice arrangement between a collaborating physician and collaborating registered professional nurse or advanced practice nurse shall be within the scope of practice of each professional and shall be consistent with each professionals skill, training, education, and competence.
(B) The collaborating physician shall consider the level of skill, education, training, and competence of the collaborating registered professional nurse or advanced practice nurse and ensure that the delegated responsibilities contained in the collaborative practice arrangement are consistent with that level of skill, education, training, and competence.
(C) The methods of treatment and the authority to administer, dispense, or prescribe drugs delegated to the collaborating registered professional nurse or advanced practice nurse in a collaborative practice arrangement shall also be consistent with the scope of practice of the collaborating physician.
(D) Guidelines for consultation and referral to the collaborating physician or designated health care facility for services or emergency care that is beyond the education, training, competence, or scope of practice of the collaborating registered professional nurse or advanced practice nurse shall be established in the collaborative practice arrangement.
(E) The methods of treatment and authority to administer, dispense, or prescribe drugs delegated to the collaborating registered professional nurse or advanced practice nurse in a collaborative practice arrangement shall not be further delegated to any other person except that the individuals identified in sections 338.095 and 338.198, RSMo may communicate prescription drug orders to a pharmacist.

(F) The methods of treatment, including any authority to administer or dispense drugs, delegated in a collaborative practice arrangement between a collaborating physician and a collaborating registered professional nurse shall be delivered only pursuant to a written agreement, jointly agreed-upon protocols, or standing orders that shall describe a specific sequence of orders, steps, or procedures to be followed in providing patient care in specified clinical situations.
(G) The methods of treatment, including any authority to administer, dispense, or prescribe drugs, delegated in a collaborative practice arrangement between a collaborating physician and a collaborating advanced practice nurse shall be delivered only pursuant to a written agreement, jointly agreed upon protocols, or standing orders that are specific to the clinical conditions treated by the collaborating physician and collaborating advanced practice nurse.
(H) The collaborative practice arrangement between a collaborating physician and a collaborating registered professional nurse or advanced practice nurse shall be signed and dated by the collaborating physician and collaborating registered professional nurse or advanced practice nurse before it is implemented, signifying that both are aware of its content and agree to follow the terms of the collaborative practice arrangement. The collaborative practice arrangement and any subsequent notice of termination of the collaborative practice arrangement shall be in writing and shall be maintained by the collaborating professionals for a minimum of eight (8) years after termination of the collaborative practice arrangement. The collaborative practice arrangement shall be reviewed and revised as needed by the collaborating physician and collaborating registered professional nurse or advanced practice nurse.
(I) Methods of treatment delegated and authority to administer, dispense, or prescribe drugs shall be subject to the following:
1. The physician retains the responsibility for ensuring the appropriate administering, dispensing, prescribing and control of drugs utilized pursuant to a collaborative practice arrangement in accordance with all state and federal statutes, rules, or regulations;
2. All labeling requirements outlined in section 338.059, RSMo shall be followed;
3. Consumer product safety laws and Class B container standards shall be followed when packaging drugs for distribution;
4. All drugs shall be stored according to the *United States Pharmacopeia* (USP) recommended conditions, which is incorporated by reference;
5. Outdated drugs shall be separated from the active inventory;
6. Retrievable dispensing logs shall be maintained for all prescription drugs dispensed and shall include all information required by state and federal statutes, rules, or regulations;
7. All prescriptions shall conform to all applicable state and federal statutes, rules, or regulations and shall include the name, address, and telephone number 0f the collaborating physician and collaborating advanced practice nurse;
8. A registered professional nurse shall not, under any circumstances, prescribe drugs;
9. An advanced practice nurse shall not, under any circumstances, prescribe controlled substances. The administering or dispensing of a controlled substance by a registered professional nurse or advanced practice nurse in a collaborative practice arrangement shall be accomplished only under the direction and supervision of the collaborating physician, or other physician designated in the collaborative practice arrangement, and shall only occur on a case-by-case determination of the patient's needs following verbal consultation between the collaborating physician and collaborating registered professional nurse or advanced practice

nurse. The required consultation and the physician's directions for the administering or dispensing of controlled substances shall be recorded in the patient's chart and in the appropriate dispensing log. These recordings shall be made by the collaborating registered professional nurse or advanced practice nurse and shall be cosigned by the collaborating physician following a review of the records;
10. An advanced practice nurse or registered professional nurse in a collaborative practice arrangement may only dispense starter doses of medication to cover a period of time for seventy-two (72) hours or less with the exception of Title X family planning providers or publicly funded clinics in community health settings that dispense medications free of charge. The dispensing of drug samples, as defined in 21 U.S.C. section 353
(c) (1), is permitted as appropriate to complete drug therapy; and
11. The medications to be administered, dispensed, or prescribed by a collaborating registered professional nurse or advanced practice nurse in a collaborative practice arrangement shall be consistent with the education, training, competence, and scopes of practice of the collaborating physician and collaborating registered professional nurse or advanced practice nurse.
(J) When a collaborative practice arrangement is utilized to provide health care services for conditions other than acute self-limited or well defined problems, the collaborating physician, or other physician designated in the collaborative practice arrangement, shall see the patient for evaluation and approve or formulate the plan of treatment for new or significantly changed conditions as soon as is practical, but in no case more than two (2) weeks after the patient has been seen by the collaborating advanced practice nurse or registered professional nurse.
(K) Nothing in these rules shall be construed to permit medical diagnosis of any condition by a registered professional nurse pursuant to a collaborative practice arrangement.
(4) Review of Services.
(A) In order to assure true collaborative practice and to foster effective communication and review of services, the collaborating physician, or other physician designated in the collaborative practice arrangement, shall be immediately available for consultation to the collaborating registered professional nurse or advanced practice nurse at all times, either personally or via telecommunications.
(B) The collaborating physician shall review the work, records, and practice of the health care delivered pursuant to a collaborative practice arrangement at least once every two (2) weeks; the collaborating physician shall document this review. This subsection shall not apply to the situation described in subsection (4)(E) below or during the time the collaborating physician and collaborating advanced practice nurse are practicing together as required in subsection (2)(C) above.
(C) If a collaborative practice arrangement is used in clinical situations where a collaborating advanced practice nurse provides health care services that include the diagnosis and initiation of treatment for acutely or chronically ill or injured persons, then the collaborating physician shall be present for sufficient periods of time, at least once every two (2) weeks, except in extraordinary circumstances that shall be documented, to participate in such review and to provide necessary medical direction, medical services,
consultations, and supervision of the health care staff. In such settings the use of a collaborative practice arrangement shall be limited to only an advanced practice nurse and the physician shall

not enter into a collaborative practice arrangement with more than three (3) full-time equivalent advanced practice nurses.
(D) The collaborating physician and collaborating registered professional nurse or advanced practice nurse shall determine an appropriate process of review and management of abnormal test results that shall be documented in the collaborative practice arrangement.
(E) In the case of collaborating physicians and collaborating registered professional nurses or advanced practice nurses practicing in settings which provide care to well patients or to those with narrowly circumscribed conditions in public health clinics or community health settings that provide population-based health services limited to immunizations, well child care, human immunodeficiency virus (HIV) and sexually transmitted disease care, family planning, tuberculosis control, cancer and other chronic disease and well-ness screenings, services related to epidemiologic investigations and prenatal care, review of services shall occur as needed and set forth in the collaborative practice arrangement. If the services provided in such settings include diagnosis and the initiation of treatment of any other disease or injury, then the provisions of subsection (4)(C) shall apply.
(F) The process and documentation of review shall be on file and maintained in the collaborative practice setting.
(G) The Missouri State Board of Registration for the Healing Arts and the Missouri State Board of Nursing separately retain the right and duty to discipline their respective licensees for violations of any state or federal statutes, rules, or regulations regardless of the licensee's participation in a collaborative practice arrangement.
(5) Population-Based Public Health Services.
(A) In the case of the collaborating physicians and collaborating registered professional nurses or advanced practice nurses practicing in association with public health clinic that provide population-based health services limited to immunizations, well child care, HIV and sexually transmitted disease care, family planning, tuberculosis control, cancer and other chronic disease and wellness screenings, services related to epidemiologic investigations and related treatment, and prenatal care, the geographic areas, methods of treatment and review of services shall occur as set forth in the collaborative practice arrangement. If the services provided in such settings include diagnosis and initiation of treatment of disease or injury not related to population-based health services, then the provisions of sections (2), (3), and (4) above shall apply.
*AUTHORITY: sections 334.104.3, RSMo Supp. 2002, and 334.125 and 335.036, RSMo 2000. * Original rule filed Jan. 29, 1996, effective Sept. 30, 1996. Amended: Filed April 1, 1998, effective Oct. 30, 1998. Amended: Filed Oct. 30, 2002, effective June 30, 2003. *Original authority: 334.104.3, RSMo 1993 amended 2002; 334.125, RSMo 1959, amended 1993, 1995; and 335.036, RSMo 1975, amended 1981, 1985, 1993, 1995, 1999.*

# Attachment 6

**CODE OF STATE REGULATIONS 1 MATT BLUNT (5/31/03)**
**Secretary of State**

# Rules of
## Department of Economic Development
## Division 200. State Board of Nursing
## Chapter 4. General Rules
### Title Page



**Chapter 4.General Rules 4 CSR 200-4 4 CSR 200-4.200 Collaborative Practice**

*PURPOSE: This rule defines collaborative practice arrangement terms and delimits geographic areas; methods of treatment; review of services; and drug/device dispensing or distribution pursuant to prescription. PUBLISHER.S NOTE: The secretary of state has determined that the publication of the entire text of the material, which is incorporated by reference as a portion of this rule, would be unduly cumbersome or expensive. Therefore, the material, which is so incorporated, is on file with the agency who filed this rule, and with the Office of the Secretary of State. Any interested person may view this material at either agency's headquarters or the same will be made available at the Office of the Secretary of State at a cost not to exceed actual cost of copy reproduction. The entire text of the rule is printed here. This note refers only to the incorporated by reference material.*

(1) For the purpose of these rules, the following definitions shall apply:
(A) Advanced practice nurse. A registered professional nurse who is also an advanced practice nurse as defined in section 335.016(2), RSMo;
(B) Collaborative practice arrangements. Refers to written agreements, jointly agreed upon protocols, or standing orders, all of which shall be in writing, for the delivery of health care services; and
(C) Registered professional nurse. A registered professional nurse as defined in section 335.016(9), RSMo, who is not an advanced practice nurse.
(2) Geographic Areas.
(A) The collaborating physician in a collaborative practice arrangement shall not be so geographically distanced from the collaborating registered professional nurse or advanced practice nurse as to create an impediment to effective collaboration in the delivery of health care services or the
adequate review of those services.
(B) The use of a collaborative practice arrangement by an advanced practice nurse who provides health care services that include the diagnosis and initiation of treatment for acutely or chronically ill or injured persons shall be limited to practice locations where the collaborating physician, or other

Physician designated in the collaborative practice arrangement, is no further than fifty (50) miles by road, using the most direct route available, from the collaborating advanced practice nurse if the advanced practice nurse is practicing in federally designated health professional shortage areas (HPSAs). Otherwise, in non-HPSAs, the collaborating physician and collaborating advanced practice nurse shall practice within thirty (30) miles by road of one another. The provision of the above specified health care services pursuant to a collaborative practice arrangement shall be limited to only an advanced practice nurse.
(C) An advanced practice nurse who desires to enter into a collaborative practice arrangement to provide health care services that include the diagnosis and treatment of acutely or chronically ill or injured persons at a location where the collaborating physician is not continuously present shall practice a the same location with the collaborating physician for a period of at least one (1) calendar month before the collaborating advanced practice nurse practices at a location where the collaborating physician is not present. The provision of the above-specified health care services pursuant to a collaborative practice arrangement shall be limited to only an advanced practice nurse. This provision applies to all collaborative practice arrangements between a physician and an advanced practice nurse unless a waiver is obtained as provided in 4 CSR 200-4.200(2)(D).
(D) If an advanced practice nurse has been continuously providing health care services pursuant to a collaborative practice arrangement with the same physician for at least one (1) year and the collaborating physician terminates the collaborative practice arrangement with less than thirty (30) days notice for reasons unrelated to the advanced practice nurse, 4 CSR 200-4.200(2)(C) may be waived by the board of nursing and the board of healing arts if the requirement for one (1) calendar month same-site collaboration would result in health care services at the location where the advanced practice nurse practices being discontinued or reduced. The request for the waiver with supporting documentation shall be submitted to the board of nursing or the board of healing arts by the advanced practice nurse or the collaborating physician and shall specify all information necessary for the board of nursing and the board of healing arts to evaluate the request including, but not limited to, the date and reasons for the termination of the collaborative practice arrangement, number of patients affected and plan for a new collaborative practice arrangement.
(3) Methods of Treatment.
(A) The methods of treatment and the authority to administer, dispense, or prescribe drugs delegated in a collaborative practice arrangement between a collaborating physician and collaborating registered professional nurse or advanced practice nurse shall be within the scope of practice of each professional and shall be consistent with each professional's skill, training, education, and competence.
(B) The collaborating physician shall consider the level of skill, education, training, and competence of the collaborating registered professional nurse or advanced practice nurse and ensure that the delegated responsibilities contained in the collaborative practice arrangement are consistent with that level of skill, education, training, and competence.
(C) The methods of treatment and the authority to administer, dispense, or prescribe drugs delegated to the collaborating registered professional nurse or advanced practice nurse in a collaborative practice arrangement shall also be consistent with the scope of practice of the collaborating physician.

(D) Guidelines for consultation and referral to the collaborating physician or designated health care facility for services or emergency care that is beyond the education, training, competence, or scope of practice of the collaborating registered professional nurse or advanced practice nurse shall be established in the collaborative practice arrangement.
(E) The methods of treatment and authority to administer, dispense, or prescribe drugs delegated to the collaborating registered professional nurse or advanced practice nurse in a collaborative practice arrangement shall not be further delegated to any other person except that the individuals identified in sections 338.095 and 338.198, RSMo may communicate prescription drug orders to a pharmacist.
(F) The methods of treatment, including any authority to administer or dispense drugs, delegated in a collaborative practice arrangement between a collaborating physician and a collaborating registered professional nurse shall be delivered only pursuant to a written agreement, jointly agreed-upon protocols, or standing orders that shall describe a specific sequence of orders, steps, or procedures to be followed in providing patient care in specified clinical situations.
(G) The methods of treatment, including any authority to administer, dispense, or prescribe drugs, delegated in a collaborative practice arrangement between a collaborating physician and a collaborating advanced practice nurse shall be delivered only pursuant to a written agreement, jointly agreed-upon protocols, or standing orders that are specific to the clinical conditions treated by the collaborating physician and collaborating advanced practice nurse.
(H) The collaborative practice arrangement between a collaborating physician and a collaborating registered professional nurse or advanced practice nurse shall be signed and dated by the collaborating physician and collaborating registered professional nurse or advanced practice nurse before it is implemented, signifying that both are aware of its content and agree to follow the terms of the collaborative practice arrangement. The collaborative practice arrangement and any subsequent notice of termination of the collaborative practice arrangement shall be in writing and shall be maintained by the collaborating professionals for a minimum of Eight (8) years after termination of the collaborative practice arrangement. The collaborative practice arrangement shall be reviewed and revised as needed by the collaborating physician and collaborating registered professional nurse or advanced practice nurse.
(I) Methods of treatment delegated and authority to administer, dispense, or prescribe drugs shall be subject to the following:
1. The physician retains the responsibility for ensuring the appropriate administering, dispensing, prescribing and control of drugs utilized pursuant to a collaborative practice arrangement in accordance with all state and federal statutes, rules, or regulations;
2. All labeling requirements outlined in section 338.059, RSMo shall be followed;
3. Consumer product safety laws and Class B container standards shall be followed when packaging drugs for distribution;
4. All drugs shall be stored according to the *United States Pharmacopeia* (USP) recommended conditions, which is incorporated by reference;
5. Outdated drugs shall be separated from the active inventory;
6. Retrievable dispensing logs shall be maintained for all prescription drugs dispensed and shall include all information regulations;

7. All prescriptions shall conform to all applicable state and federal statutes, rules, or regulations and shall include the name, address, and telephone number of the collaborating physician and collaborating advanced practice nurse;
8. A registered professional nurse shall not, under any circumstances, prescribe drugs;
9. An advanced practice nurse shall not, under any circumstances, prescribe controlled substances. The administering or dispensing of a controlled substance by a registered professional nurse or advanced practice nurse in a collaborative practice arrangement shall be accomplished only under the direction and supervision of the collaborating physician, or other physician designated in the collaborative practice arrangement, and shall only occur on a case-by-case determination of the patient's needs following verbal consultation between the collaborating physician and collaborating registered professional nurse or advanced practice nurse. The required consultation and the physician's directions for the administering or dispensing of controlled substances shall be recorded in the patient's chart and in the appropriate dispensing log. These recordings shall be made by the collaborating registered professional nurse or advanced practice nurse and shall be co-signed by the collaborating physician following a review of the records;
10. An advanced practice nurse or registered professional nurse in a collaborative practice arrangement may only dispense starter doses of medication to cover a period of time for seventy-two (72) hours or less with the exception of Title X family planning providers or publicly funded clinics in community health settings that dispense medications free of charge. The dispensing of drug samples, as defined in 21 U.S.C. section 353 (c)(1), is permitted as appropriate to complete drug therapy; and
11. The medications to be administered, dispensed, or prescribed by a collaborating registered professional nurse or advanced practice nurse in a collaborative practice arrangement shall be consistent with the education, training, competence, and scopes of practice of the collaborating physician and collaborating registered professional nurse or advanced practice nurse.
(J) When a collaborative practice arrangement is utilized to provide health care services for conditions other than acute self-limited or well defined problems, them collaborating physician, or other physician designated in the collaborative practice arrangement, shall see the patient for evaluation and approve or formulate the plan of treatment for new or significantly changed conditions as soon as is practical, but in no case more than two (2) weeks after the patient has been seen by the collaborating advanced practice nurse or registered professional nurse.
(K) Nothing in these rules shall be construed to permit medical diagnosis of any condition by a registered professional nurse pursuant to a collaborative practice arrangement.
(4) Review of Services.
(A) In order to assure true collaborative practice and to foster effective communication and review of services, the collaborating physician, or other physician designated in the collaborative practice arrangement, shall be immediately available for consultation to the collaborating registered professional nurse or advanced practice nurse at all times, either personally or via telecommunications.
(B) The collaborating physician shall review the work, records, and practice of the health care delivered pursuant to a collaborative practice arrangement at least once every two (2) weeks. The collaborating physician shall document this review. This subsection shall not apply to the

situation described in subsection (4)(E) below or during the time the collaborating physician and collaborating advanced practice nurse are practicing together as required in subsection (2)(C) above.
(C) If a collaborative practice arrangement is used in clinical situations where a collaborating advanced practice nurse provides health care services that include the diagnosis and initiation of treatment for acutely or chronically ill or injured persons, then the collaborating physician shall be present for sufficient periods of time, at least once every two (2) weeks, except in extraordinary circumstances that shall be documented, to participate in such review and to provide necessary medical direction, medical services, consultations, and supervision of the health care staff. In such settings the use of a collaborative practice arrangement shall be limited to only an advanced practice nurse and the physician shall not enter into a collaborative practice arrangement with more than three (3) full-time equivalent advanced practice nurses.
(D) The collaborating physician and collaborating registered professional nurse or advanced practice nurse shall determine an appropriate process of review and management of abnormal test results, which shall be documented in the collaborative practice arrangement.
(E) In the case of collaborating physicians and collaborating registered professional nurses or advanced practice nurses practicing in settings which provide care to well patients or to those with narrowly circumscribed conditions in public health clinics or community health settings that provide population-based health services limited to immunizations, well child care, human immunodeficiency virus (HIV) and sexually transmitted disease care, family planning, tuberculosis control, cancer and other chronic disease and well- ness screenings, services related to epidemiologic investigations and prenatal care, review of services shall occur as needed and set forth in the collaborative practice arrangement. If the services provided in such settings include diagnosis and the initiation of treatment of any other disease or injury, then the provisions of subsection (4)(C) shall apply.
(F) The process and documentation of review shall be on file and maintained in the collaborative practice setting.
(G) The Missouri State Board of Registration for the Healing Arts and the Missouri State Board of Nursing separately retain the right and duty to discipline their respective licensees for violations of any state or federal statutes, rules, or regulations regardless of the licensee's participation in a collaborative practice arrangement.
(5) Population-Based Public Health Services.
(A) In the case of the collaborating physicians and collaborating registered professional nurses or advanced practice nurses practicing in association with public health clinics that provide population-based health services limited to immunizations, well child care, HIV and sexually transmitted disease care, family planning, tuberculosis control, cancer and other chronic disease and wellness screenings, services related to epidemiologic investigations and related treatment, and prenatal care, the geographic areas, methods of treatment and review of services shall occur as set forth in the collaborative practice arrangement. If the services provided in such settings include diagnosis and initiation of treatment of disease or injury not related to population-based health services, then the provisions of sections (2), (3), and (4) above shall apply.

Attachment 7-1

*Missouri Revised Statutes*

# Chapter 190
# Emergency Services
# Section *190.500*

August 28, 2002

**Temporary license--qualified health care professions--declared emergency.**
190.500. 1. Notwithstanding any other provision of law to the contrary, a temporary license may be issued for no more than a twelve-month period by the appropriate licensing board to any otherwise qualified health care professional licensed and in good standing in another state and who meets such other requirements as the licensing board may prescribe by rule and regulation, if the health care professional:
(1) Is acting pursuant to federal military orders under Title X for active duty personnel or Title XXXII for national guard members; and
(2) Is enrolled in an accredited training program for trauma treatment and disaster response in a hospital in this state; or
(3) If the health care professional is acting pursuant to the governor's declaration of an emergency as defined in section 44.010, RSMo, such temporary licensure shall be issued pursuant to this subdivision for a two-week period and, upon license verification, may be reissued every two weeks thereafter.
2. Licensure information and confirmation of health care professionals acting pursuant to this section may be obtained by any available means, including electronic mail.
3. For purposes of this section, the term "health care professional" shall have the same meaning as such term is defined in section 383.130, RSMo.

(L. 1999 H.B. 343 § 6, A.L. 2001 H.B. 431, A.L. 2002 S.B. 712 merged with S.B. 714)

Attachment 7-2

SECOND REGULAR SESSION

**[**TRULY AGREED TO AND FINALLY PASSED**]**

HOUSE COMMITTEE SUBSTITUTE FOR

# SENATE BILL NO. 714

**91ST GENERAL ASSEMBLY**

2002

2938L.05T

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# AN ACT

To repeal section 190.500, RSMo, relating to the declaration of a state public health emergency, and to enact in lieu thereof one new section relating to the same subject.

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*Be it enacted by the General Assembly of the State of Missouri, as follows:*

Section A. Section 190.500, RSMo, is repealed and one new section enacted in lieu thereof, to be known as section 190.500, to read as follows:

190.500. **1.** Notwithstanding any other provision of law to the contrary, a temporary license may be issued for no more than a twelve-month period by the appropriate licensing board to any otherwise qualified health care professional licensed **and in good standing** in another state and who meets such other requirements as the licensing board may prescribe by rule and regulation, if the health care professional:

(1) Is acting pursuant to federal military orders under Title X for active duty personnel or Title XXXII for **[**military reservists**]** **national guard members**; and

(2) Is enrolled in an accredited training program for trauma treatment and disaster response in a hospital in this state**; or**

**(3) If the health care professional is acting pursuant to the governor's declaration of an emergency as defined in section 44.010, RSMo, such temporary licensure shall be issued pursuant to this subdivision for a two-week period and, upon license verification, may be reissued every two weeks thereafter**.

**2. Licensure information and confirmation of health care professionals acting pursuant to this section may be obtained by any available means, including electronic mail.**

**3. For purposes of this section, the term "health care professional" shall have the same meaning as such term is defined in section 383.130, RSMo.**

Attachment 8

## HEALTH ASSESSMENT FORM FOR ANTHRAX
(SAMPLE FORM)

***Rx*** _____

Date of Report:_____ Patient Identifying Number: _____
**Patient Information:** (Please check only one: ☐ SSN ☐ Passport # ☐ Drivers license #)

Name:_____ Age:_____ Date of Birth:_____
Home Address:_____
Telephone Number: Home:_____ Work:_____
Current Address:_____
Telephone: _____

**Medical History:**
Allergies to Medications: Yes ☐ No ☐
If yes, please list medications:_____
_____

Have you ever had any of the following medical conditions?
*HIV/AIDS* Yes ☐ No ☐
*Hepatitis* Yes ☐ No ☐ Kidney *Disease* Yes ☐ No ☐

Are you presently taking any medications, including over the counter medications? If yes, please list them:
_____
_____
_____

Have you ever had a serious reaction after receiving any medication? Yes ☐ No ☐
If yes, please specify the medication received, the approximate date, what happen, and what was done in response to the reaction: _____
_____
_____

**Females Only:**
Are you currently pregnant? Yes ☐ No ☐
Are you breast-feeding? Yes ☐ No ☐
Are you currently using any form of birth control? Yes ☐ No ☐
If so, please check the appropriate box: ☐ Oral Contraceptive ☐ Patch Contraceptive
☐ Other Methods, please specify: _____

Signature for Treatment_____ Date_____

***Do Not Write Below This Box***

☐ Ciprofloxacin Dose_____ Lot Number_____ Quantity_____

☐ Doxycycline Dose_____ Lot Number_____ Quantity_____

☐ Amoxacillin Dose_____ Lot Number_____ Quantity_____

Health Care Professional's Signature_____ Date_____

## Attachment 9

# Preparing Oral Suspensions of Ciprofloxacin and Doxycycline

The purpose of this appendix is to help state/local pharmacy staffs prepare ciprofloxacin and doxycycline oral suspensions during a biological terrorist event. We provide systematic, simple instructions that people with limited compounding skills can follow. For those who wish to investigate the subject of oral suspensions further, we recommend the Paddock Laboratories, Inc., web page at

http://www.paddocklabs.com/publications/secundum/secart21.html.[1]

***We want to thank the pharmacy of Children's Healthcare of Atlanta, which helped us prepare the ciprofloxacin portion of this appendix, and the pharmacy of ScripTech, LLC, which helped us prepare the doxycycline portion.***

## COMPOUNDING CIPROFLOXACIN ORAL SUSPENSION

The instructions below produce 100 ml of 50-mg/ml ciprofloxacin hydrochloride oral suspension. If your mortar and pestle allow, you can double or triple ingredient quantities if you are able to triturate sufficient tablets. Typically, however, the size of your mortar and pestle will limit the amount of tablets that you can crush, wet, and suspend at one time. Mechanized equipment can speed the process and becomes increasingly important if you need to prepare large quantities.
Our instructions use 500 mg Bayer brand ciprofloxacin (Cipro) tablets, which are in the SNS. This tablet contains 500 mg of the active drug component. Our instructions do not require sieving, although the tablet contains a thin film coating.

### Ingredients

The following ingredients prepare 100 ml of ciprofloxacin hydrochloride oral suspension in a strength of 50 mg/ml:

- Active ingredient: 10 Bayer Cipro 500 mg tablets
- Wetting agent: distilled water
- Suspending agent: Ora-Plus (Paddock Laboratories), 50 ml

[1] See, for example, J. Ellinghuysen et al., "Preparation of Oral Suspensions and Syrups: Basic Concepts," *Secundum Artem*, Vol. 2, No 1 (available from Paddock Laboratories website). Another source of information is a memorandum from R. McIntosh, Subject: "Formulation for Compounding Doxycycline Suspension," March 27, 2001.

- ***Vehicle: Ora-Sweet (Paddo ck Laboratories), to fill to (q.s.) to a final volume of 100 ml.***
- ***Directions***

1. Triturate tablets in a mortar with pestle

Finely grind tablets with a ceramic or Wedgwood mortar and pestle. The finer the powder, the better the suspension. The resultant powder should be uniform in color and particle size.

2. Wet powder with distilled water (CRITICAL STEP)

Wet the powder mass with a MINIMAL amount of water to form a thick viscous paste. A common mistake in compounding suspensions is to use too much wetting agent. Add water gradually to ensure minimal use and a thick paste. The mass should be smooth and uniform with no lumps when you are done.

3. Add 50 ml of Ora-Plus in geometric dilution

Add Ora-Plus to the powder in ever-increasing amounts, working in each addition until you form a uniform mix. The volume of the first addition of Ora-Plus should be similar to that of the Cipro/water paste. Geometric dilution means that each addition of Ora-Plus should approximately equal the volume of mixture in the mortar until you add all 50 ml.

We suggest you use Ora-Plus as your suspending agent. Its physical characteristics make it easer to achieve proper volume than some suspending agents. Veegum is a viable alternative to Ora-Plus for this recipe. Other agents may work in an emergency after trial and error. Make sure you carefully inspect the resultant product for desired physical characteristics.

4. Q.S. to 100 ml with Ora-Sweet

Transfer the mixture from step 3 into the final container and use Ora-Sweet as the vehicle to "wash" out the mortar. Add Ora-Sweet in portions to the empty mortar to lift any drug mixture that sticks to the mortar's walls. Gradually add the washes to the final container. Top off the final container with Ora-Sweet to the desired volume and shake well. It is helpful to use a container that is slightly larger than the final desired volume for this step to allow for even dispersion after vigorous shaking.

We recommend Ora-Sweet in this step. It is a berry-flavored vehicle that masks the bitter taste of drugs. It is compatible with Ora-Plus because the same manufacturer makes both. You may find it more convenient to compound a volume that intentionally exceeds the desired dispensing volume so that you can pour the final volume directly from the mortar to the dispensing container even though some mixture will stick to the mortar walls.

Alternatives to Ora-Sweet are cherry syrup, USP; sorbitol 70%; and simple syrup, USP. Cherry syrup, USP is a good substitute because it effectively masks drug taste. If you use sorbitol or simple syrup, USP, you need to add a flavoring agent because their sweetness alone does not mask drug taste.

To achieve the proper final volume, you need to include the volume of the flavoring agent. A 3 to 4 ml addition of cherry flavor, USP (not the same as syrup) should be sufficient.

Taste the final product to confirm its sweetness. If it is unpleasant, make adjustments. Flavoring is very important to achieve patient compliance. Not all flavorings mask the taste of drugs equally. Cherry and berry flavors usually work well at hiding bitter drug taste, as does unsweetened Kool-Aid powder. Add small amounts of the flavoring until you mask the drug's bitterness.

The bitterness of ciprofloxacin suspension made from tablets makes it a particular challenge. Several compounding pharmacists have told us that it is very difficult to mask its bitter taste. They indicated that the flavorings we suggest above might not be acceptable to all patients. We suggest that you try giving patients a dose dab of Hershey's syrup (assuming no chocolate allergy) before and after administering the suspension. This is common practice in children's hospitals. We also suggest that the dispensing pharmacist witness the administration of the first dose to ensure compliance.

5. Label the container

Label the container as follows:
Do not freeze, store in refrigerator.
Preparation is stable for 2 months in refrigerator.
Shake well before use.
We suggest you mark filling levels (based on patient weight) on the reusable calibrated oral dosing syringes in the SNS and use them to dispense this suspension**.**

# COMPOUNDING DOXYCYCLINE HYCLATE ORAL SUSPENSION

The instructions below produce 60 ml of doxycycline hyclate oral suspension in a strength of 10 mg/ml. If your mortar and pestle allow, you can double or triple ingredient quantities if you are able to triturate sufficient tablets. Typically, however, the size of your mortar and pestle will limit the amount of tablets that you can crush, wet, and suspend at one time. Mechanized equipment can speed the process and becomes increasingly important if you need to prepare large quantities.
Our instructions use Zenith-Goldline and Schein brands of doxycycline tablet, which are in the SNS. These brands do not contain excessive film coatings or other formulation characteristics that require additional preparation steps, (e.g., sieving). This may not be true for other brands of doxycycline tablet. Note that a 100 mg doxycycline hyclate tablet contains 100 mg of doxycycline. Thus, you do not have to make complicated adjustments to compensate for the hyclate portion in the tablet to deliver 100% active drug component.

## Ingredients

The ingredients below prepare doxycycline hyclate oral suspension, 10 mg/ml, 60 ml:

- Active ingredient: 6 Doxycycline hyclate tablets
- Wetting agent: glycerin, USP, 1 ml
- Suspending agent: Ora-Plus (Paddock Laboratories), 30 ml
- Vehicle: Ora-Sweet (Paddock Laboratories), to q.s. to final volume (60 ml).

To provide flexibility, we mention some alternatives to the wetting agent, suspending agent, and vehicle in the directions.
Directions

1. Triturate tablets in a mortar with pestle

Finely grind tablets with a ceramic or Wedgwood mortar and pestle. The finer the powder, the better the suspension. The resultant powder should be uniform in color and particle size.

2. Wet powder with 1 ml glycerin (CRITICAL STEP)

Wet the powder mass with MINIMAL amounts of glycerin to form a thick viscous paste (you may not need the full 1 ml). Adding too much wetting agent is a common mistake in compounding suspensions. Add glycerin gradually to ensure minimal use and a thick paste. The mass should be smooth and uniform with no lumps when you are done.

If glycerin, USP is not available, you may also use ethanol, docusate sodium liquid, and Ora-Plus as wetting agents. Ora-Plus is primarily a suspending agent but you can also use it as a wetting agent. Whichever wetting agents you use, make sure you produce a smooth, uniform, thick paste.

3. Add 30 ml Ora-Plus in geometric dilution

Add Ora-Plus to the paste in ever-increasing amounts, working in each addition until you form a uniform mix. The volume of the first addition of Ora-Plus should be similar to that of the doxy/glycerin paste. Geometric dilution means that each addition of Ora-Plus should approximately equal the volume of mixture in the mortar until you add all 30 ml.

We suggest you use Ora-Plus as your suspending agent. Its physical characteristics make it easer to achieve proper volume than some suspending agents. ScripTech suggests no alternatives to Ora-Plus for this recipe. Therefore, we recommend no alternatives. Other agents may work in an emergency after trial and error. Make sure you carefully inspect the resultant product for desired physical characteristics.

*4.* Q.S. to 60 ml with Ora-Sweet Transfer the mixture from step 3 into the final container and use Ora-Sweet as the vehicle to "wash" out the mortar. Add Ora-Sweet in portions to the empty mortar to lift any drug mixture that sticks to the mortar's walls. Gradually add the washes to the final container. Top off the final container with Ora-Sweet to the desired volume and shake well. It is helpful to use a container that is slightly larger than the final desired volume for this step to allow for even dispersion after vigorous shaking.

We recommend Ora-Sweet in this step. It is a berry-flavored vehicle that masks the bitter taste of drugs. It is compatible with Ora-Plus because the same manufacturer makes both. You may find it more convenient to compound a volume that intentionally exceeds the desired dispensing volume so that you can pour the final volume directly from the mortar to the dispensing container even though some mixture will stick to the mortar walls.

Alternatives to Ora-Sweet are cherry syrup, USP; sorbitol 70%; and simple syrup, USP. Cherry syrup, USP is a good substitute because it effectively masks drug taste. If you use sorbitol or simple syrup, USP, you need to add a flavoring agent because their sweetness alone does not mask drug taste.

To achieve the proper final volume, you need to include the volume of the flavoring agent. A 2 ml addition of cherry flavor, USP (not the same as syrup) should be sufficient.

Taste the final product to confirm its sweetness. If it is unpleasant, make adjustments. Flavoring is very important to achieve patient compliance. Not all flavorings mask the taste of drugs equally. Cherry and berry flavors work especially well at hiding bitter drug taste. Unsweetened Kool-Aid powder also works well as a flavoring agent. Add small amounts of it until you mask the drug's bitterness.

5. Label the container

Label the container as follows:
Do not freeze, store in refrigerator.
Preparation is stable for 2 months in refrigerator.
Shake well before use.
We suggest you mark filling levels (based on patient weight) on the reusable calibrated oral dosing syringes in the SNS and use them to dispense this suspension.
(reference from version 9 manual from the SNS Program)

# Attachment 10

| Dispensing | Status | Date completed |
|---|---|---|
| Define/describe your local policies for the following: | | |
| Allowing an adult to pick up prophylaxis for other household members or individuals | | |
| The information that will go on drug labels for distributing, agency, prescriber, and 24-hour information number | | |
| The prophylactic regimens that will be used to treat various threats | | |
| Describe/identify the location, number, facilities, equipment, staffing, and logistics support of dispensing sites that will provide prophylaxis to the community before the onset of symptoms for a worst-case, community-wide attack scenario | | |
| Describe how dispensing procedures will change for a limited scale event | | |
| Describe the process, information, and staff assignments you will use at each dispensing site to efficiently process the public through the site | | |
| Describe where you will get sufficient staff of pharmacists, doctors, nurses, and other professionals such as interpreters and sign language personnel | | |
| Describe where you will get the significant numbers of volunteers that each dispensing site will need to operate | | |
| Describe how you plan to transport the public to dispensing sites during a large-scale attack to avoid the congestion that would result if everyone drives (optional depending on the site) | | |
| Describe procedures for completing English and other language prescription labels given the different types of labels that exist for different packaged medicines | | |
| Describe the method you will use to preprint and/or quickly reproduce sufficient quantities of labels, patient information sheets, forms, and handouts required by each dispensing site | | |
| Describe how you will efficiently and quickly ascertain the health information of persons in line and others (e.g., family members who are unable to come to dispensing) to support the issue of a specific drug | | |
| Describe the method you will use to track patients, the drug/lot they receive, the person who hands drugs to them, and the dispensing site where they received their drug | | |
| Describe the method you will use to inform large populations of undocumented aliens (if they exist) about the importance of coming to dispensing | | |
| Attachment 10 -- Dispensing (continued) | Status | Date completed |

| | | |
|---|---|---|
| Describe the method you will use to deliver prophylactic medicines to those who cannot use dispensing sites | | |
| Confirm the presence of a comprehensive public health communications plan in your All Hazards or Bioterrorism Response Plan that provides clear, written, health information to the public such as multi-language TV and radio public information announcements | | |
| Describe the informational materiels, forms, scripts, and videos each dispensing site will need to issue prophylaxis to the public. In your description, ensure that you identify how you will reproduce during an emergency more of the materiel if it is required | | |
| Confirm that the state regional planners know the above information | | |
| Describe the process that communicates changes to the above to state regional planners | | |
| Coordinate with Treatment Centers | Status | Date completed |
| Describe how public health authorities, hospital networks, and individual treatment centers plan to respond to various scales, types, and locations of attack | | |
| Describe the resources you will need to support each of the above scenarios | | |
| Describe the procedures/reports/information SNS functions need during an emergency to adequately support treatment centers | | |

# Frequently Asked Questions

**The following are questions that are frequently asked about the SNS program:**

- How many ventilators are in a 12-hour Push Package?

➢ There are no ventilators in a 12-hour Push Package, but the SNS assets it contains include several products to assist with airway management (e.g., adult and child manual pulmonary resuscitators). If the event requires it, quantities of ventilators (up to 4,000) can be shipped in immediate follow-up to the 12-hour Push Package. The DHSS will identify the quantity needed when the SNS is requested. The ventilators would be shipped in specialized air cargo containers with required ancillary supplies. Each ventilator will come with a pediatric adaptor, its won instruction manual, and a brief instructional videotape to facilitate rapid and proper use of this device.

- Do you have a training video or other operator information about the use of ventilators in the SNS?

➢ The ventilator in the SNS is the Uni-Vent Eagle, Model 754, manufactured by IMPACT Instrumentation, Inc. This unit was selected because of its ease of use. If your direct care providers and response teams want more information about this unit, we can help obtain training materials for it or you can contact the company at http://www.impactinstrumentation.com or (973) 882-1212.

- Can the SNS ship directly to our dispensing sites once we have established them?

➢ The answer depends on the magnitude of an event. During a large-scale event that requires a large number of dispensing sites, the SNS will be shipped only to the RSS site(s). However, for events where the number of dispensing sites is small, such as the anthrax attacks in the fall 2001, the SNS might be able to be shipped directly. The federal SNS Program will need to know the specific shipping address and the name and phone number of a contact person at each dispensing site. They will also need to know that your sites are safe and secure. Direct shipment to a local dispensing site must come through the DHSS DSR.

- What prepackaged oral medications are in the SNS for dispensing to children and adults?

➢ A 12-hour Push Package comes with more than 200,000 10-day unit-of-use regimens that may preclude or delay the need to repackage SNS bulk medicines. These include childproof bottles of a mix of ciprofloxacin, doxycycline, and amoxicillin tablets. We include amoxicillin for pregnant women and children who cannot chew. Each tablet has a groove, making it easy to split in half for the lower dosage levels; ciprofloxacin, doxycycline, and amoxicillin oral suspension is also included.

- Should we create a list of locally available antibiotics for prophylaxis or treatment before the SNS arrives?

➢ It is very important that you know what antibiotics you have and where you have them so you can begin responding effectively in the early hours of an emergency before the SNS arrives. During that period, you will probably want to protect the people who are essential to your emergency response (first responders and others) so they will be ready to protect the rest of the community when the SNS arrives. You need to know if you have enough oral antibiotics to do that. You also need to know your capabilities for responding if the first sign of an attack is large numbers of individuals showing up in emergency rooms. To treat these individuals, you will probably need items such as ciprofloxacin IV, doxycycline IV, gentamicin IV, IV administration sets, catheters, IV piggyback solution, and 1,000 ml 0.9% NaCl solution. Hospitals normally stock relatively small quantities of these items and depend on their distributors to deliver what they need as they need it. Unfortunately, distributors also hold relatively little stock of these items (e.g., 30 days of routine demand) and depend on manufacturers to provide what they need when they need it.

- Will we have to reimburse CDC for SNS medications that we use during an emergency?

➢ No. The federal SNS Program has procured the medications in the SNS for distribution. They will not charge you nor will they expect you to charge patients for the SNS medications they receive or the supplies that you expend on their behalf. Charges for professional services to administer medications are a matter beyond the purview of the SNS Program.

- Can we use contents of the SNS materiel to replenish local pharmacies for medications used to treat first responders before the SNS arrives?

➢ No. The SNS Program has stated that medications are not to be used to replenish local stock.

- May a state request more than one 12-hour Push Package?

➢ In some circumstances, two 12-hour Push Packages may be appropriate and in others, large quantities of specific items may be appropriate, particularly if we have identified the specific threat. The final decision on what to ship will depend on information gathered from federal, state, and local participants.

- Does the SNS include oxygen and oxygen equipment and supplies?

➢ No. The SNS does not have oxygen in either the 12-hour Push Package or VMI.

# Emergency/Terrorism Response Information: Selected Internet Sites

## Comprehensive Web Sites

Emergency/Terrorism Response (DHSS)
http://www.dhss.state.mo.us/BT_Response/BT_Response.html

Emergency Preparedness & Response (CDC)
http://www.bt.cdc.gov/index.asp

Center for the Study of Bioterrorism (Saint Louis University)
http://www.bioterrorism.slu.edu/index.html

## Biological Agents

Biological Agents/Diseases (CDC)
http://www.bt.cdc.gov/agent/agentlist.asp

Biological Agents/Toxins/Diseases (DHSS)
http://www.dhss.state.mo.us/BT_Response/MedicalProfessionals.htm#General

U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)
http://www.usamriid.army.mil/

## Chemical Agents

Chemical Agents (CDC)
http://www.bt.cdc.gov/agent/agentlistchem.asp

Chemical Agents (DHSS)
http://www.dhss.state.mo.us/BT_Response/MedicalProfessionals.htm#GenInfoChem

Agency for Toxic Substances and Disease Registry (ATSDR)
http://www.atsdr.cdc.gov/

## Radiological Events

Radiation Emergencies (CDC)
http://www.bt.cdc.gov/radiation/index.asp

Radiological Emergencies (DHSS)
http://www.dhss.state.mo.us/BT_Response/MedicalProfessionals.htm#GenInfoRad

Radiation Emergency Assistance Center/Training Site (REAC/TS)
http://www.orau.gov/reacts/default.htm

## Other Web Sites

Missouri Homeland Security
http://www.homelandsecurity.state.mo.us/

U.S. Department of Homeland Security
http://www.dhs.gov/dhspublic/

Mass Trauma Preparedness and Response Information (CDC)
http://www.cdc.gov/masstrauma/default.htm

Strategic National Stockpile (CDC)
http://www.bt.cdc.gov/stockpile/index.asp

Disaster Readiness (American Hospital Association)
http://www.hospitalconnect.com/aha/key_issues/disaster_readiness/index.html

CDC = Centers for Disease Control & Prevention
DHSS = Missouri Department of Health & Senior Services

Center for Emergency Response/Terrorism, Missouri Department of Health & Senior Services, September 2003
http://www.dhss.state.mo.us/BT_Response/BT_Response.html

**Table 4.** Recommended Therapy for Inhalational Anthrax Infection in the Mass Casualty Setting or for Postexposure Prophylaxis*

| Category | Initial Oral Therapy† | Alternative Therapy if Strain Is Proved Susceptible | Duration After Exposure, d |
|---|---|---|---|
| Adults | Ciprofloxacin, 500 mg orally every 12 h | Doxycycline, 100 mg orally every 12 h‡<br>Amoxicillin, 500 mg orally every 8 h§ | 60 |
| Children | Ciprofloxacin, 20-30 mg/kg per d orally taken in 2 daily doses, not to exceed 1 g/d‖ | Weight ≥20 kg: amoxicillin, 500 mg orally every 8 h§<br>Weight <20 kg: amoxicillin, 40 mg/kg taken orally in 3 doses every 8 h§ | 60 |
| Pregnant women¶ | Ciprofloxacin, 500 mg orally every 12 h | Amoxicillin, 500 mg orally every 8 h§ | 60 |
| Immunosuppressed persons | Same as for nonimmunosuppressed adults and children | | |

*Some of these recommendations are based on animal studies or in vitro studies and are not approved by the US Food and Drug Administration.
†In vitro studies suggest ofloxacin (400 mg orally every 12 hours, or levofloxacin, 500 mg orally every 24 hours) could be substituted for ciprofloxacin.
‡In vitro studies suggest that 500 mg of tetracycline orally every 6 hours could be substituted for doxycycline. In addition, 400 mg of gatifloxicin or monifloxacin, both fluoroquinolones with mechanisms of action consistent with ciprofloxacin, taken orally daily could be substituted.
§According to the Centers for Disease Control and Prevention recommendations, amoxicillin is suitable for postexposure prophylaxis only after 10 to 14 days of fluoroquinolones or doxycycline treatment and then only if there are contraindications to these 2 classes of medications (eg, pregnancy, lactating mother, age <18 years, or intolerance of other antibiotics).
‖Doxycycline could also be used if antibiotic susceptibility testing, exhaustion of drug supplies, adverse reactions preclude use of ciprofloxacin. For children heavier than 45 kg, adult dosage should be used. For children lighter than 45 kg, 2.5 mg/kg of doxycycline orally every 12 hours should be used.
¶See "Management of Pregnant Population" for details.

Inglesby TV, O'Toole T, Henderson DA, et al. Anthrax as a biological weapon, 2002. *JAMA* 2002;287:2236-52.

**Table 2.** Working Group Recommendations for Treatment of Patients With Pneumonic Plague in the Contained and Mass Casualty Settings and for Postexposure Prophylaxis*

| Patient Category | Recommended Therapy |
|---|---|
| | **Contained Casualty Setting** |
| Adults | Preferred choices<br>Streptomycin, 1 g IM twice daily |
| | Gentamicin, 5 mg/kg IM or IV once daily or 2 mg/kg loading dose followed by 1.7 mg/kg IM or IV 3 times daily† |
| | Alternative choices<br>Doxycycline, 100 mg IV twice daily or 200 mg IV once daily |
| | Ciprofloxacin, 400 mg IV twice daily‡ |
| | Chloramphenicol, 25 mg/kg IV 4 times daily§ |
| Children‖ | Preferred choices<br>Streptomycin, 15 mg/kg IM twice daily (maximum daily dose, 2 g) |
| | Gentamicin, 2.5 mg/kg IM or IV 3 times daily† |
| | Alternative choices<br>Doxycycline,<br>If ≥45 kg, give adult dosage |
| | If <45 kg, give 2.2 mg/kg IV twice daily (maximum, 200 mg/d) |
| | Ciprofloxacin, 15 mg/kg IV twice daily‡ |
| | Chloramphenicol, 25 mg/kg IV 4 times daily§ |
| Pregnant women¶ | Preferred choice<br>Gentamicin, 5 mg/kg IM or IV once daily or 2 mg/kg loading dose followed by 1.7 mg/kg IM or IV 3 times daily† |
| | Alternative choices<br>Doxycycline, 100 mg IV twice daily or 200 mg IV once daily |
| | Ciprofloxacin, 400 mg IV twice daily‡ |
| | **Mass Casualty Setting and Postexposure Prophylaxis#** |
| Adults | Preferred choices<br>Doxycycline, 100 mg orally twice daily†† |
| | Ciprofloxacin, 500 mg orally twice daily‡ |
| | Alternative choice<br>Chloramphenicol, 25 mg/kg orally 4 times daily§** |
| Children‖ | Preferred choice<br>Doxycycline,††<br>If ≥45 kg, give adult dosage |
| | If <45 kg, then give 2.2 mg/kg orally twice daily |
| | Ciprofloxacin, 20 mg/kg orally twice daily |
| | Alternative choices<br>Chloramphenicol, 25 mg/kg orally 4 times daily§** |
| Pregnant women¶ | Preferred choices<br>Doxycycline, 100 mg orally twice daily†† |
| | Ciprofloxacin, 500 mg orally twice daily |
| | Alternative choices<br>Chloramphenicol, 25 mg/kg orally 4 times daily§** |

*These are consensus recommendations of the Working Group on Civilian Biodefense and are not necessarily approved by the Food and Drug Administration. See "Therapy" section for explanations. One antimicrobial agent should be selected. Therapy should be continued for 10 days. Oral therapy should be substituted when patient's condition improves. IM indicates intramuscularly; IV, intravenously.

†Aminoglycosides must be adjusted according to renal function. Evidence suggests that gentamicin, 5 mg/kg IM or IV once daily, would be efficacious in children, although this is not yet widely accepted in clinical practice. Neonates up to 1 week of age and premature infants should receive gentamicin, 2.5 mg/kg IV twice daily.

‡Other fluoroquinolones can be substituted at doses appropriate for age. Ciprofloxacin dosage should not exceed 1 g/d in children.

§Concentration should be maintained between 5 and 20 μg/mL. Concentrations greater than 25 μg/mL can cause reversible bone marrow suppression.[35,62]

‖Refer to "Management of Special Groups" for details. In children, ciprofloxacin dose should not exceed 1 g/d, chloramphenicol should not exceed 4 g/d. Children younger than 2 years should not receive chloramphenicol.

¶Refer to "Management of Special Groups" for details and for discussion of breastfeeding women. In neonates, gentamicin loading dose of 4 mg/kg should be given initially.[63]

#Duration of treatment of plague in mass casualty setting is 10 days. Duration of postexposure prophylaxis to prevent plague infection is 7 days.

**Children younger than 2 years should not receive chloramphenicol. Oral formulation available only outside the United States.

††Tetracycline could be substituted for doxycycline.

Inglesby TV, Dennis DT, Henderson DA, et al. Plague as a biological weapon. *JAMA*. 2000;283:2281-90.

## Tularemia

**Table 3.** Working Group Consensus Recommendations for Treatment of Patients With Tularemia in a Mass Casualty Setting and for Postexposure Prophylaxis*

| Mass Casualty Recommended Therapy |
|---|
| **Adults** |
| Preferred choices |
| Doxycycline, 100 mg orally twice daily |
| Ciprofloxacin, 500 mg orally twice daily† |
| **Children** |
| Preferred choices |
| Doxycycline; if ≥45 kg, give 100 mg orally twice daily; if <45 kg, give 2.2 mg/kg orally twice daily |
| Ciprofloxacin, 15 mg/kg orally twice daily†‡ |
| **Pregnant Women** |
| Preferred choices |
| Ciprofloxacin, 500 mg orally twice daily† |
| Doxycycline, 100 mg orally twice daily |

*One antibiotic, appropriate for patient age, should be chosen from among alternatives. The duration of all recommended therapies in Table 3 is 14 days.
†Not a US Food and Drug Administration–approved use.
‡Ciprofloxacin dosage should not exceed 1 g/d in children.

Dennis DT, Inglesby TV, Henderson DA, et al. Tularemia as a biological weapon. *JAMA* 2001;285:2763-73.